DIVISION 104, PART 5,

SHERMAN FOOD, DRUG, AND COSMETIC LAWS

Effective January 1, 2000

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CHAPTER 1. GENERAL PROVISIONS AND DEFINITIONS

109875. This part shall be known as the Sherman Food, Drug, and Cosmetic Law.

109880. Unless the context otherwise requires, the definitions set forth in this article govern the construction of this part.

109885. "Advertisement" means any representations, including, but not limited to, statements upon the products, its packages, cartons, and any other container, disseminated in any manner or by any means, for the purpose of inducing, or that is likely to induce, directly or indirectly, the purchase or use of any food, drug, device, or cosmetic.

109890. "Antibiotic drug" means any drug intended for use by man or other animal and that contains any quantity of any chemical substance produced by a micro-organism or the chemically synthesized equivalent and that, in dilute solutions, has the capacity to inhibit or destroy micro-organisms.

109895. "Color additive" means a substance that satisfies both of the following requirements:

(a) It is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source.

(b) When added or applied to a food, drug, device, or cosmetic, or to the human body or any part of the body, it is capable, alone or through reaction with any other substance, of imparting color to the food, drug, device, or cosmetic, or to the human body or the part of the human body, to which it is added or applied.

The term "color additive" does not include any material that the department, by regulation, determines is used, or intended to be used, solely for a purpose or purposes other than coloring.

The term "color," as used in this section, includes black, white, and intermediate grays.

This section does not apply to any pesticide chemical, soil, or plant nutrient, or other agricultural chemical, solely because of its effect in aiding, retarding, or otherwise affecting, directly or indirectly, the growth or other natural physiological process of produce of the soil and thereby affecting its color, whether before or after harvest.

109900. "Cosmetic" means any article, or its components, intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to, the human body, or any part of the human body, for cleansing, beautifying, promoting attractiveness, or altering the appearance.

The term "cosmetic" does not include soap.

109905. "Counterfeit", as used in respect to any food, drug, device, or cosmetic, means a food, drug, device, or cosmetic that bears or whose package or labeling bears,

without authorization, the trademark, trade name, or other identifying mark, imprint, or device, or any likeness or trademark, trade name, or other identifying mark, imprint, or device of a manufacturer, processor, packer, or distributor, other than the actual manufacturer, processor, packer, or distributor, or that falsely purports or is represented to be the product of, or to have been packed or distributed by, the other manufacturer, processor, packer, or distributor.

109910. "Department" means the State Department of Health Services.

109915. "Director" means the State Director of Health Services.

109920. "Device" means any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, that is any of the following:

(a) Recognized in the official National Formulary or the United States Pharmacopoeia, or any supplement to them.

(b) Intended for use in the diagnosis of disease or other condition, or in the cure, mitigation, treatment, or prevention of disease in humans or any other animal.

(c) Intended to affect the structure or any function of the body of humans or any other animal and that does not achieve any of its principal intended purposes through chemical action within or on the body of humans or other animals and that is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

109925. "Drug" means any of the following:

(a) Any article recognized in an official compendium.

(b) Any article used or intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or any other animal.

(c) Any article other than food, that is used or intended to affect the structure or any function of the body of human beings or any other animal.

(d) Any article used or intended for use as a component of any article designated in subdivision (a), (b), or (c) of this section.

The term "drug" does not include any device.

Any food for which a claim, (as described in Sections 403(r) (1)(B) (21 U.S.C. Sec. 343(r)(1)(B)) and 403(r)(3) (21 U.S.C. Sec. 343(r)(3)) or Sections 403(r)(1)(B) (21 U.S.C. Sec. 343(r) (1)(B)) and 403(r)(5)(D) (21 U.S.C. Sec. 343(r)(5)(D)) of the federal act), is made in accordance with the requirements set forth in Section 403(r) (21 U.S.C. Sec. 343(r)) of the federal act, is not a drug under subdivision (b) solely because the label or labeling contains such a claim.

109930. "Federal act" means the federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. Sec. 301 et seq.).

109935. "Food" means any of the following:

(a) Any article used or intended for use for food, drink, confection, condiment, or chewing gum by man or other animal.

(b) Any article used or intended for use as a component of any article designated in subdivision (a).

109940. "Food additive" means any substance, the intended use of which results or may reasonably be expected to result, directly or indirectly, in the substance becoming a component of the food or otherwise affecting characteristics of the food. This includes any substance or radiation source intended for use in producing, manufacturing, packing, treating, packaging, transporting, or holding any food.

The term "food additive" does not include any of the following:

(a) A pesticide chemical in or on a raw agricultural commodity.

(b) A pesticide chemical that is used, or intended for use, in the production, storage, or transportation of any raw agricultural commodity.

(c) A color additive.

(d) Any substance used in accordance with a sanction or approval granted prior to the enactment of the Food Additives Amendment of 1958 (72 Stat. 1784), pursuant to the federal act; the Poultry Products Inspection Act (71 Stat. 441; 21 U.S.C. Sec. 451 et seq.); the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended and extended (21 U.S.C. Sec. 71 et seq.); or the Food and Agricultural Code of this state.

109945. "Food and drug inspector" means any authorized agent of the Bureau of Food and Drug of the department, who shall have the powers set forth in Section 106500.

109947. "Food processing facility" means any facility operated for the purposes of manufacturing, packing, or holding processed food. Food processing facility does not include a food facility as defined in Section 113785, or any facility exclusively storing, handling, or processing dried beans.

109950. "Immediate container" does not include any package liner.

109955. "Label" means a display of written, printed, or graphic matter upon a food, drug, device, or cosmetic or upon its immediate container.

109960. "Labeling" means any label or other written, printed, or graphic matter upon a food, drug, device, or cosmetic or upon its container or wrapper, or that accompanies any food, drug, device, or cosmetic.

109965. "Local health department" means the health department of a city, county, city and county, or local health district that qualifies for state assistance pursuant to Chapter 3 (commencing with Section 101175) of Part 3 of Division 101, or any city health department of a city that has had its own health department for 12 years or more.

109970. "Manufacture" means the preparation, compounding, propagation, processing, or fabrication of any food, drug, device, or cosmetic. The term "manufacture" includes repackaging or otherwise changing the container, wrapper, or labeling of any food, drug, device, or cosmetic in furtherance of the distribution of the food, drug, device, or

cosmetic. The term "manufacture" does not include repackaging from a bulk container by a retailer at the time of sale to its ultimate consumer.

109975. "New device" means any of the following:

(a) Any device the composition, construction, or properties of which are such that the device is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of devices, as having been adequately shown, through scientific investigations to be safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling or advertising thereof.

(b) Any device the composition, construction, or properties of which are such that the device, as a result of such investigation to determine its safety and effectiveness for use under these conditions, has become so recognized, but which has not, otherwise than in the investigations, been used to a material extent or for a material time under the conditions.

109980. "New drug" means either of the following:

(a) Any drug the composition of which is such that the drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling or advertising thereof.

(b) Any drug the composition of which is such that the drug, as a result of investigations to determine its safety and effectiveness for use under these conditions, has become so recognized, but that has not, otherwise than in the investigations, been used to a material extent or for a material time under the conditions.

109985. "Official compendium" means the latest edition of the United States Pharmacopoeia, the latest edition of the Homeopathic Pharmacopoeia of the United States, or the latest edition of the National Formulary, or any supplement to any of these.

109990. "Package" means any container or wrapper that may be used by a manufacturer, producer, jobber, packer, or dealer for enclosing or containing any food, drug, device, or cosmetic.

The term "package" does not include any of the following:

(a) Any shipping container or outer wrapping used solely for the transportation of a food, drug, device, or cosmetic in bulk quantity to any manufacturer, packer, processor, or wholesale or retail distributor.

(b) Any shipping container or outer wrapping used by any retailer to ship or deliver any food, drug, device, or cosmetic to any retail consumer if the container or wrapping bears no printed matter pertaining to any food, drug, device, or cosmetic.

109995. "Person" means any individual, firm, partnership, trust, corporation, limited liability company, company, estate, public or private institution, association, organization, group, city, county, city and county, political subdivision of this state, other

governmental agency within the state, and any representative, agent, or agency of any of the foregoing.

110000. "Pesticide chemical" means any substance that alone, in chemical combination, or in formulation with one or more substances, is an "economic poison" within the meaning of Section 12753 of the Food and Agricultural Code of this state or the Federal Insecticide, Fungicide, and Rodenticide Act (61 Stat. 163; 7 U.S.C. Sec. 135 et seq.), and that is used in the production, storage, or transportation of any raw agricultural commodity.

110005. "Potentially hazardous food" means any food capable of supporting growth of infectious or toxigenic micro-organisms when held at temperatures above 45 degrees Fahrenheit.

110010. "Prescription" means an oral order given individually for the patient for whom prescribed directly from the prescriber to the furnisher or indirectly by means of a written order signed by the prescriber that bears the name and address of the prescriber, the license classification of the prescriber, the name and address of the patient, the name and quantity of drug or device prescribed, the directions for use, and the date of issue.

110015. "Principal display panel" means that part of a label most likely to be displayed, presented, shown, or examined under normal and customary conditions of display for retail sale.

110020. "Raw agricultural commodity" means any food in its raw or natural state. It includes, but is not limited to, any fruit that is washed, colored, or otherwise treated in its unpeeled natural form prior to marketing.

110025. "Substantial evidence" means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug or device involved, on the basis of that it could be fairly and responsibly concluded by the experts that the drug or device will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling, proposed labeling, or advertising of any drug or device.

110030. The provisions of this part regarding the selling of any food, drug, device, or cosmetic include, but are not limited to, all of the following:

(a) The manufacture, production, processing, and packing of any food, drug, device, or cosmetic.

(b) The exhibition, offer, possession, or holding of any food, drug, device, or cosmetic for sale, dispensing, giving, supplying, or applying in the conduct of any establishment.

(c) The sale, dispensing, giving, supplying, or applying of any food, drug, device, or cosmetic in the conduct of any establishment.

110035. All regulations pertaining to any food, drug, device, or cosmetic adopted by the department that are in effect on the effective date of this part shall remain in effect until the department adopts regulations pursuant to this part which repeal the regulations.

110040. This part shall be so construed as to not be in conflict with the Food and Agricultural Code, or with the Alcoholic Beverage Control Act, Division 9 (commencing with Section 23000) of the Business and Professions Code, and the regulations adopted pursuant thereto.

CHAPTER 2. ADMINISTRATION

ARTICLE 1. General

110045. The department shall administer and enforce this part.

110050. The Food Safety Fund is hereby created as a special fund in the State Treasury. All moneys collected by the department under subdivision (c) of Section 110466 and Sections 110470 and 110485 and under Article 7 (commencing with Section 110810) of Chapter 5 shall be deposited in the fund, for use by the department, upon appropriation by the Legislature, for the purposes of providing funds necessary to carry out and implement the inspection provisions of this part relating to food, the provisions relating to education and training in the prevention of microbial contamination pursuant to Section 110485, and the registration provisions of Article 7 (commencing with Section 110810) of Chapter 5.

110055. All money collected by the department under Sections 111830, 111885, and 111905 shall be deposited into the State Treasury to the credit of the General Fund.

110060. The director and authorized agents of the department shall have the powers set forth in Sections 100165 and 106500.

110065. The department may adopt any regulations that it determines are necessary for the enforcement of this part. The regulations shall be adopted by the department in the manner prescribed by Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code. The department shall, insofar as practicable, make these regulations conform with those adopted under the federal act or by the United States Department of Agriculture or by the Internal Revenue Service of the United States Treasury Department.

110070. Whenever public health or other considerations in this state require, the department may adopt, upon its own motion, or upon the petition of any interested party, regulations that prescribe tolerances, included but not limited to zero tolerances, for poisonous or deleterious substances, food additives, pesticide chemicals, or color additives. The department may also prescribe the conditions under which a food additive or a color additive may be safely used and may grant exemptions for a food

additive or color additive when it is to be used solely for investigational or experimental purposes.

A petitioner shall establish, by data submitted to the department, that a necessity exists for such regulations and that its effect will not be detrimental to the public health. If the data furnished by the petitioner is not sufficient to allow the department to determine whether such regulations should be adopted, the department may require additional data to be submitted. Failure to comply with this requirement shall be sufficient grounds to deny the request.

110075. In adopting regulations, pursuant to Section 110070 of this part, the department shall consider all of the following factors that the petitioner shall furnish:

(a) The name and all pertinent information concerning the poisonous or deleterious substance, food additive, pesticide chemical, or color additive, including its chemical identity and composition, its proposed use, including directions, recommendations, and suggestions, its proposed labeling, and all other relevant data bearing on its physical or other technical effect, and the quantity required to produce that effect.

(b) The probable composition of any substance formed in or on a food, drug, device, or cosmetic resulting from the use of the substance.

(c) The probable consumption and effect of the substance in the diet of man or any other animal.

(d) Safety factors that, in the opinion of qualified experts, are generally recognized as appropriate for the use of animal experimentation data.

(e) Practicable methods of analysis for determining the identity and quantity of all of the following:

(1) Any substance which is in or on the food, drug, device, or cosmetic.

(2) Any substance formed in or on the food, drug, device, or cosmetic because of the use of the substance.

(3) The pure substance and its anticipated breakdown products and impurities.

(f) Facts supporting the contention that the use of the substance will serve a useful purpose.

110080. (a) All pesticide regulations and any amendments to these regulations adopted pursuant to the federal act or the Food and Agricultural Code, in effect on November 23, 1970, or adopted on or after this date, are the pesticide regulations in this state. The department may, by regulation, prescribe tolerances for pesticides in processed foods in this state whether or not these tolerances are in accordance with the regulations adopted pursuant to the federal act or the Food and Agricultural Code.

(b) Except as otherwise provided in this subdivision, the department shall evaluate the tolerance prescribed, or an exemption from a tolerance granted, for a pesticide in processed foods and make a determination whether or not the existing tolerance, or the exemption from a tolerance, is protective of the public health whenever any one of the following occurs:

(1) The Director of Food and Agriculture designates the pesticide as a restricted material pursuant to subdivisions (a) and (b) of Section 14004.5 of the Food and Agricultural Code.

(2) The Director of Food and Agriculture refuses to register or cancels the registration of the pesticide pursuant to Section 12825, or suspends the registration of the pesticide pursuant to Section 12826, of the Food and Agricultural Code, upon determining that the pesticide is detrimental to the public health and safety.

(3) The Director of Food and Agriculture adopts regulations restricting worker entry into areas treated with the pesticide pursuant to Section 12981 of the Food and Agricultural Code.

(4) The pesticide is the subject of a proceeding pursuant to a determination by the Environmental Protection Agency under paragraph (3)(i)(A), (3)(ii)(A), (3)(ii)(B), or (3)(iii) of subsection (a) of Section 162.11 of Title 40 of the Code of Federal Regulations.

The requirement to evaluate a tolerance prescribed, or an exemption from a tolerance granted, for a pesticide does not apply if the department finds that any of the actions described in paragraphs (1) to (4), inclusive, occurred for reasons that are not related to the question whether or not the existing tolerance, or the exemption from a tolerance, adequately protects the public health. If the department makes such a finding, the reasons for the finding shall be stated in writing.

(c) The determination required by subdivision (b), and the reasons for the determination, shall be stated in writing. If the determination is required because any of the actions described in paragraphs (1) to (4), inclusive, of subdivision (b) occurs after January 1, 1985, the determination shall be completed within one year of the date of the action. If the determination is required because any of those actions occurred prior to January 1, 1985, the determination shall be completed by January 1, 1990.

(d) In any case where the department, after consultation with the Department of Food and Agriculture, determines, pursuant to subdivision (b), that the tolerance prescribed, or an exemption from a tolerance granted, for a pesticide is not protective of the public health, the department shall, if it does not act immediately pursuant to subdivision (a), transmit notice of its determination to the responsible federal agencies and shall request that they take action, pursuant to the federal act, to modify the tolerance or an exemption from a tolerance. If, after one year from the date the notice is transmitted, the department finds that the responsible federal agencies have failed to take appropriate action to protect the public health, the department shall exercise its authority pursuant to subdivision (a) to prescribe a tolerance that is protective of the public health and shall notify the responsible federal agencies of its action.

110085. All food additive regulations and any amendments to the regulations adopted pursuant to the federal act in effect on November 23, 1970, or adopted on or after that date, are the food additive regulations of this state. The department may, by regulation, prescribe conditions under which a food additive may be used in this state whether or not these conditions are in accordance with the regulations adopted pursuant to the federal act.

110090. All color additive regulations and any amendments to the regulations adopted pursuant to the federal act, in effect on November 23, 1970, or adopted on or after that date, are the color additive regulations of this state. The department may, by regulation, prescribe conditions under which a color additive may be used in this state whether or

not those conditions are in accordance with regulations adopted pursuant to the federal act.

110095. All special dietary use regulations and any amendments to regulations adopted pursuant to the federal act, in effect on November 23, 1970, or adopted on or after that date, are the special dietary use regulations of this state. If the department finds that it is necessary to inform purchasers of the value of a food for special dietary use, it may adopt any special dietary use regulation, whether or not the regulation is in accordance with the regulations adopted pursuant to the federal act.

110100. (a) All food labeling regulations and any amendments to those regulations adopted pursuant to the federal act, in effect on January 1, 1993, or adopted on or after that date shall be the food labeling regulations of this state.

(b) The department may, by regulation, adopt additional food labeling regulations. Prior to the adoption of any food labeling regulation pursuant to this subdivision, the department shall seek comments from consumer groups and representatives of the food industry that have been identified by the department as being affected by the proposed regulation.

110105. All good manufacturing practices regulations for any food, drug, device, or cosmetic and any amendments to the regulations adopted pursuant to the federal act in effect on November 23, 1970, or adopted on or after such date, are the good manufacturing practices regulations of this state. If the department finds that it is necessary for the protection of consumers, it may adopt interpretative regulations as necessary to define "current good manufacturing practice" as used in this part.

110110. (a) All regulations relating to (1) new drug applications, except for abbreviated new drug applications, adopted pursuant to Section 505 of the federal act (21 U.S.C. Sec. 355), (2) applications for premarket approval of new devices, adopted pursuant to Section 515 of the federal act (21 U.S.C. Sec. 360e), and (3) postmarketing reports, recordkeeping, and other postapproval requirements for approved new drug applications or approved new device premarket approval applications, adopted pursuant to the federal act, that are in effect on January 1, 1993, or that are adopted on or after that date, shall be the new drug and new device application regulations of this state.

(b) The department may, by regulation, adopt any new drug or new device application regulation that it determines is necessary for the administration and enforcement of this part, whether or not the regulation is in accordance with the regulations adopted pursuant to the federal act.

110115. A federal regulation adopted pursuant to this part takes effect in this state 30 days after it becomes effective as a federal regulation. Any person who will be adversely affected by adoption of the federal regulation in this state may, within the 30 days prior to its becoming effective in this state, file with the department, in writing, objections and a request for a hearing. The timely filing of substantial objections to a regulation that has become effective under the federal act, stays the adoption of the regulation in this state.

110120. If no substantial objections are received and no hearing is requested within 30 days after publication of a newly proposed state regulation, it shall take effect on the date set by the department. The effective date shall be at least 60 days after the time for filing objections has expired.

110125. If substantial objections are made to a federal regulation within 30 days prior to its becoming effective in this state or to a proposed regulation within 30 days after it is published, the department, after notice, shall conduct a public hearing to receive evidence on issues raised by the objections. Any interested person or his or her representative may be heard. The department shall act upon objections by order and shall mail the order to objectors by certified mail as soon after the hearing as practicable. The order shall be based on evidence contained in the record of the hearing. If the order concerns a federal regulation, the department may adopt, rescind, or modify it. If the order concerns a proposed regulation, the department may withdraw it or set an effective date for the regulation as published or as modified by the order. The effective date shall be at least 60 days after publication of the order.

110130. Hearings authorized or required by this part shall be conducted by the department or agent as the department may designate for that purpose.

110135. Before any alleged violation of this part is reported to the Attorney General, a district attorney, or a city attorney for the institution of a criminal proceeding, the person against whom this proceeding is contemplated may be given appropriate notice and an opportunity to show cause why he or she should not be prosecuted and to present additional facts that may mitigate the action. The showing may be presented either orally or in writing, in person, or by attorney.

ARTICLE 2. Inspection and Sampling

110140. For purposes of enforcement of this part, any authorized agent of the department may, upon presenting appropriate credentials and at a reasonable time, do any of the following:

(a) Enter any factory, warehouse, or establishment in which any food, drug, device, or cosmetic is manufactured, packed, or held; enter any vehicle that is being used to transport or hold the food, drug, device, or cosmetic; or enter any place where any food, drug, device, or cosmetic is suspected of being held in violation of this part.

(b) Inspect any factory, warehouse, establishment, vehicle, or place, and all pertinent equipment, raw material, finished and unfinished materials, containers, and labeling in the factory, warehouse, establishment, vehicle, or place. In the case of any factory, warehouse, establishment, or consulting laboratory in which any food, drug, device, or cosmetic is manufactured, packed, or held, inspection shall include any record, file, paper, process, control, and facility that has a bearing on whether the food, drug, device, or cosmetic is adulterated or misbranded, or falsely advertised within the meaning of this part or whether it has been or is being manufactured, packed, transported, sold, or offered for sale in violation of this part.

110145. The inspection authorized by Section 110140 shall not include any of the following:

(a) Financial data.

(b) Sales data, other than shipment data.

(c) Pricing data.

(d) Personnel data, except data as to qualifications of technical and professional personnel.

(e) Research data, except data relating to any new drug or antibiotic drug that is subject to reporting and inspection under this part or the federal act.

110150. An authorized agent of the department may secure any sample or specimen of any food, drug, device, or cosmetic. If the agent obtains any samples prior to leaving the premises, he or she shall leave a receipt describing any sample obtained.

110155. An authorized agent of the department shall have access to all records of carriers in commerce relating to the movement in commerce of any food, drug, device, or cosmetic, or the holding of that food, drug, device, or cosmetic during or after the movement, and the quantity, shipper, and consignee of the food, drug, device, or cosmetic. Evidence obtained under this section shall not be used in a criminal prosecution of the person from whom it is obtained. The carrier shall not be subject to the other provisions of this part by reason of their receipt, carriage, holding, or delivery of any food, drug, device, or cosmetic in the usual course of business as carriers.

110160. It is unlawful for any person to refuse to permit entry or inspection, the taking of samples or other evidence, or access to copying of any record as authorized by this part, or to conceal the samples or evidence, or withhold evidence concerning them.

110165. It is unlawful for any person to use to his or her own advantage, or to reveal to any person other than to the director or officers or employees of this department, or to the courts when relevant in any judicial proceeding under this part, any information acquired under authority of this part concerning any method or process which as a trade secret is entitled to protection.

ARTICLE 3. Publicity

110170. The department may publish reports summarizing all judgments and court orders that have been rendered under this part, including the nature of the charge and the disposition of the charge.

110175. The department may distribute information regarding any food, drug, device, or cosmetic as the department considers necessary for the protection of the health and safety of the consumer or for his or her protection from fraud.

110180. The department may collect, report, or illustrate the results of any investigation of the department.

ARTICLE 4. Export Documents

110190. Any person who ships to another state or country a food, drug, device, or cosmetic manufactured or produced in this state may request the department to issue an export document to reference the shipment of the food, drug, device, or cosmetic. The food, drug, device, or cosmetic shall be manufactured or produced in this state by a person who has a valid registration, license, certificate, or permit issued by the department under this part or the Miscellaneous Food, Food Facility, and Hazardous Substances Act (Section 27). For each request, the requesting person shall submit to the department all of the following:

(a) All original labels, labeling, and advertising affixed to, accompanying, or relating to the food, drug, device, or cosmetic. The department may accept copies if submission of original labels, labeling, or advertising is impractical.

(b) If not clearly evident from the materials submitted pursuant to subdivision (a), the requester shall submit both of the following:

(1) The name, place of business, and the type and number of the registration, license, certificate, or permit issued by the department to the manufacturer or producer of the food, drug, device, or cosmetic.

(2) The identity of the food, drug, device, or cosmetic being shipped.

(c) The name of the state or country to which the food, drug, device, or cosmetic is being shipped.

(d) The approximate date of shipment of the food, drug, device, or cosmetic.

(e) Additional statements the requesting person wishes to have incorporated into the export document.

(f) The name and telephone number of the requesting person to whom the department may refer questions or requests for additional information.

(g) The one-time fee required by paragraph (1) of subdivision (a) of Section 110210, if the fee has not yet been paid, and the minimum charge required by paragraph (2) of subdivision (a) of Section 110210.

110200. (a) Each export document issued by the department shall do all of the following:

(1) Identify either or both of the following:

(A) The name and place of business of the manufacturer or producer of the food, drug, device, or cosmetic.

(B) The name and place of business of the distributor of the food, drug, device, or cosmetic.

(2) Identify the food, drug, device, or cosmetic being shipped.

(3) Identify the state or country to which the food, drug, device, or cosmetic is being shipped.

(4) Identify the approximate date of shipment.

(5) Describe the department's authority over the food, drug, device, or cosmetic to be shipped and its manufacturer or producer.

(6) State that the department does not object to the sale of the food, drug, device, or cosmetic in this state or the shipment of the food, drug, device, or cosmetic to any other state or country.

(b) Each export document issued by the department may, in the department's sole discretion, include additional statements requested by the person who requested the export document.

(c) Each export document issued by the department shall be issued by the Chief of the Food and Drug Branch of the department, or his or her designee. The chief or his or her designee may issue an export document prepared by the department or by the requesting person.

(d) The export document shall expire 180 days after its issue date.

110210. (a) Each person requesting the department to issue an export document shall pay nonreturnable fees as follows:

(1) A one-time fee of one hundred dollars ($100).

(2) A fee for service charge at the rate of eighty dollars ($80) per hour, at a minimum of twenty-five dollars ($25) per request.

(3) Any attendant costs incurred by the department, including, but not limited to, the costs of additional inspection, priority mailing, or notary service necessitated by the request.

(b) The fee amounts shall be adjusted annually pursuant to Section 100425.

(c) In no case shall the fees exceed the reasonable costs of the department in administering this article.

(d) The department shall provide to the person who pays the fees a statement or invoice that describes the costs paid from the fees.

110220. (a) The department may refuse to accept any request where the information required to be submitted by this article is incomplete.

(b) The department may refuse to issue an export document, or may invalidate an export document, if it finds, or has probable cause to believe, any of the following:

(1) The food, drug, device, or cosmetic, or requesting person violated any provision of this part, the Miscellaneous Food, Food Facility, and Hazardous Substances Act (Section 27), or any regulation adopted pursuant to this part or that act.

(2) Any information required to be submitted by this article is incomplete or false.

(3) The requesting person has not paid all outstanding fees required by this article.

(4) The food, drug, device, or cosmetic is not manufactured or produced in this state.

(5) The food, drug, device, or cosmetic is intended to be exported under 110655, 110790, 111315, 111460, 111720, or 111785.

(6) The food is a raw agricultural commodity or dairy product regulated by the Department of Food and Agriculture or a poultry or meat product regulated by the United States Department of Agriculture.

(c) If the department refuses to issue an export document, or invalidates an export document, the department shall inform the requesting person in writing of the reasons for the refusal or invalidation. The requesting person may request

reconsideration by forwarding a written request to the Chief of the Division of Environmental Health of the department. The request for reconsideration must be postmarked or received by the department no later than 30 days after the date of the department's refusal or invalidation, and shall include a complete statement of all arguments and evidence that support the request for reconsideration. The Chief of the Division of Environmental Health shall notify the requesting person of his or her decision within 30 days. The decision of the Chief of the Division of Environmental Health shall be final.

(d) It is the intent of the Legislature that the department shall respond to each request for issuance of an export document within five working days of receipt of the request by the Food and Drug Branch of the department.

110225. It is unlawful for any person to knowingly supply the department with false material facts in a request for an export document or to falsely represent that the department has issued an export document.

110230. Any person who has a valid registration, license, certificate, or permit issued by the department to manufacture or produce a food, drug, device, or cosmetic in this state may request the department to issue an official copy of the valid registration, license, certificate, or permit.

110235. (a) Each person requesting the department to issue an official copy of a valid registration, license, certificate, or permit shall pay nonreturnable fees as follows:

(1) Fifteen dollars ($15) per official copy.

(2) Any attendant costs incurred by the department, including, but not limited to, the costs of additional inspection, priority mailing, or notary service necessitated by the request.

(b) The fee amount shall be adjusted annually pursuant to Section 100425.

(c) The department shall provide to the person who pays the fees a statement or invoice that describes the costs paid from the fees.

110240. There is established an Export Document Program Fund within the General Fund. All fees collected pursuant to Sections 110210 and 110235 shall be deposited into the Export Document Program Fund and, upon appropriation, shall be expended by the department for the purpose of administering this article.

CHAPTER 3. GUARANTEES

110245. No dealer shall be prosecuted under this part for a violation concerning any food, drug, device, or cosmetic that is contained in an original, unbroken, and undamaged package that bears the original labeling if all of the following requirements are satisfied:

(a) He or she has used reasonable care in the storage and handling of the food, drug, device, or cosmetic.

(b) He or she received the food, drug, device, or cosmetic in the usual channels of trade as first-class merchantable stock and not as seconds or damaged articles or job lots purchased under conditions that indicate that the food, drug, device, or cosmetic was not usual first-class merchandise.

(c) He or she can produce a guarantee to the effect that the food, drug, device, or cosmetic is not adulterated, misbranded, or falsely advertised, within the meaning of this part, or that it is not a food, drug, device, or cosmetic which, pursuant to this part, may not be sold or offered for sale in this state.

110250. The guarantee shall be dated prior to the date of sale of the food, drug, device, or cosmetic and it shall be signed by the wholesaler, jobber, manufacturer, or other person located or residing in this state from whom the dealer received the food, drug, device, or cosmetic in good faith.

110255. A guarantee may be either a general guarantee or a special guarantee and shall be produced prior to the time of reporting an alleged violation to the Attorney General, the district attorney, or a city attorney for prosecution.

110260. A general guarantee shall guarantee without condition or restriction any food, drug, device, or cosmetic that is produced, prepared, compounded, packed, distributed, or sold by the guarantor as not adulterated, mislabeled, misbranded, falsely advertised, or that the article is not an article under this part that may not be sold or offered for sale.

110265. A special guarantee shall guarantee in the same manner as a general guarantee the particular food, drug, device, or cosmetic listed in an invoice of the food, drug, device, or cosmetic, and shall be attached to, or shall fully identify, the invoice.

110270. All guarantees shall contain the name and address of the guarantor making the sale of food, drug, device, or cosmetic. A guarantee shall protect the person only when the food, drug, device, or cosmetic covered by the guarantee remains identical, both as to composition and labeling, with the food, drug, device, or cosmetic as composed and labeled when originally received from the guarantor.

110275. It is unlawful for any person to give a guarantee or undertaking that is false.

100280. If the guarantee is to the effect that the food, drug, device, or cosmetic is not in violation within the meaning of the federal act, it shall be sufficient for all the purposes of this part, and shall have the same force and effect as though it referred to this part, unless, pursuant to this part, the standard for the food, drug, device, or cosmetic concerned is higher than the standard for a like food, drug, device, or cosmetic under the federal act. In that case, this part shall prevail over the federal act.

110285. In any case where the department has adopted a regulation prescribing a tolerance, including, but not limited to, a zero tolerance, for a poisonous or deleterious substance, food additive, pesticide chemical, or color additive in processed foods, the department may require manufacturers to guarantee that foods they market in the state

comply with the tolerance. The department may require a guarantee periodically but in no case more often than once each calendar quarter.

CHAPTER 4. PACKAGING, LABELING, AND ADVERTISING

ARTICLE 1. General

110290. In determining whether the labeling or advertisement of a food, drug, device, or cosmetic is misleading, all representations made or suggested by statement, word, design, device, sound, or any combination of these, shall be taken into account. The extent that the labeling or advertising fails to reveal facts concerning the food, drug, device, or cosmetic or consequences of customary use of the food, drug, device, or cosmetic shall also be considered.

110295. The requirement that any word, statement, or other information appear on the label shall not be considered to be complied with unless the word, statement, or other information also appears on the outside container or wrapper of the retail package of any food, drug, device, or cosmetic, or is easily legible through the outside container or wrapper.

110300. It is unlawful for any person to forge, counterfeit, simulate, falsely represent, or without proper authority use, any mark, stamp, tag, label, or other identification device that is authorized or required by regulations adopted pursuant to this part or the federal act.

110305. It is unlawful for any person to use on the labeling of any drug or device, or any advertisement relating to any drug or device, any representation or suggestion that an application with respect to the drug or device is effective under Section 111550 or that the drug or device complies with that section.

110310. It is unlawful for any manufacturer, packer, or distributor of a prescription drug or device offered for sale in this state to fail to maintain for transmittal or to fail to transmit to any practitioner licensed by applicable state law to administer the drug or device who makes written request for information as to the drug or device true and correct copies of all printed matter that is required to be included in any package in which that drug or device is distributed or sold. Nothing in this section shall be construed to exempt any person from any labeling requirement imposed by or under other provisions of this part.

110315. It is unlawful for any person, with the intent to deceive, to place, or cause to be placed upon any food, drug, device, or cosmetic, or its package, the trade name or other identifying mark or imprint of another person or any likeness of the trade name or other identifying mark or imprint of another person.

110320. It is unlawful for any person to sell, dispense, dispose of, hold, or conceal any food, drug, device, or cosmetic or its package, with knowledge that the trade name or other identifying marks, imprint, or likeness of the trade name or other identifying mark or imprint of another person has been placed on the food, drug, device, or cosmetic or its package in a manner prohibited by Section 110315.

110325. It is unlawful for any person to possess, make, sell, dispose of, cause to be made, or conceal any punch, die, plate, or other device that may be used to render a food, drug, device, or cosmetic or its package or labeling a counterfeit.

110330. It is unlawful for any person to do any act that causes any food, drug, device, or cosmetic to be a counterfeit, or to sell, dispense, or hold for sale or dispensing, the counterfeit food, drug, device, or cosmetic.

110335. The department may adopt regulations exempting from any labeling or packaging requirements of this part any food, drug, device, or cosmetic that is in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed and packed, on condition that the food, drug, device, or cosmetic is not adulterated or misbranded under the provisions of this part upon removal from the processing, labeling, or repacking establishment. Such food, drug, device, or cosmetic is subject to all other applicable provisions of this part.

All regulations relating to the exemptions that are in effect on the effective date of this part, or that are adopted on or after that date, pursuant to the federal act, are automatically effective in this state. The department may, however, adopt any additional regulations concerning exemptions.

ARTICLE 2. Fair Packaging and Labeling

110340. All labels of foods, drugs, devices, or cosmetics shall conform with the requirements of the declaration of net quantity of contents of Section 4 of the Fair Packaging and Labeling Act (80 Stat. 1296; 15 U.S.C., Sec. 1451) and the regulations adopted pursuant thereto. Foods, drugs, devices, and cosmetics exempted from the requirements of Section 4 of the Fair Packaging and Labeling Act, however, are also exempt from this article.

110345. The label of any package of a food, drug, device, or cosmetic that bears a representation as to the number of servings of the commodity contained in the package shall bear a statement of the net quantity, in terms of weight, measure, or numerical count, of each serving.

110350. It is unlawful for any person to distribute, or cause to be distributed, in commerce any packaged food, drug, device, or cosmetic if any qualifying words or phrases appear in conjunction with the separate statement of the net quantity of contents required by Section 110340.

This section, however, does not prohibit supplemental statements, at other places on the package, describing in nondeceptive terms the net quantity of contents. Such supplemental statements of net quantity of contents shall not include any term qualifying a unit of weight, measure, or count that tends to exaggerate the amount of the commodity contained in the package.

110355. Whenever the department determines that regulations containing prohibitions or requirements, other than those prescribed by Section 110340, are necessary to prevent the deception of consumers or to facilitate value comparisons as to any food, drug, device, or cosmetic, the department shall adopt regulations with respect to that commodity.

110360. The department may establish and define standards for the characterization of the size of a package that encloses any food, drug, device, or cosmetic, that may be used to supplement the label statement of net quantity of contents of packages containing the commodity. This section, however, does not authorize any limitation on the size, shape, weight, dimension, or number of packages that may be used to enclose any food, drug, device, or cosmetic.

110365. The department may regulate the placement upon any package that contains any food, drug, device, or cosmetic or upon any label affixed to the article, of any printed matter stating or representing by implication that the article is offered for retail sale at a price lower than the ordinary and customary retail sale price or that a retail sale price advantage is accorded to any purchaser of the article by reason of the size of that package or the quantity of its contents.

110370. The department may require that the label on each package of a food, drug, device, or cosmetic bear the common or usual name of the article, if any, and in case the article consists of two or more ingredients, the common or usual name of each ingredient listed in order of decreasing predominance by weight. This section, however, does not require that any trade secret be divulged.

110375. The department may prohibit the nonfunctional slack fill of packages containing any food, drug, device, or cosmetic.

As used in this section, "nonfunctional slack-filled" means that a package is filled to substantially less than its capacity for any reason other than any of the following:

(a) Protection of the contents of the package.

(b) The requirements of machines used for enclosing the contents in the package.

110380. All regulations and their amendments pertaining to foods, drugs, devices, and cosmetics that are in effect on the effective date of this part, or that are adopted on or after that date, pursuant to the Fair Packaging and Labeling Act (80 Stat. 1296; 15 U.S.C. Sec. 1451 et seq.) shall be the regulations of this state. The department may, when necessary, prescribe any packaging and labeling regulation for foods, drugs, devices, and cosmetics whether or not the regulation is in accordance with regulations

adopted under the Fair Packaging and Labeling Act. No regulations shall be adopted that are contrary to the labeling requirements for the net quantity of contents required pursuant to Section 4 of the Federal Fair Packaging and Labeling Act and the regulations adopted pursuant to that section.

110385. It is unlawful for any person to distribute in commerce any food, drug, device, or cosmetic, if its packaging or labeling does not conform to the provisions of this article or to regulations adopted pursuant to this article. This section does not apply to persons engaged in business as wholesale or retail distributors of foods, drugs, devices, or cosmetics, except to the extent that they are engaged in the packaging or labeling of the commodities or they prescribe or specify the manner in which the commodities are packaged or labeled. This section shall not be construed to repeal, invalidate, or supersede any other section of this part.

ARTICLE 3. Advertising

110390. It is unlawful for any person to disseminate any false advertisement of any food, drug, device, or cosmetic. An advertisement is false if it is false or misleading in any particular.

110395. It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any food, drug, device, or cosmetic that is falsely advertised.

110398. It is unlawful for any person to advertise any food, drug, device, or cosmetic that is adulterated or misbranded.

110400. It is unlawful for any person to receive in commerce any food, drug, device, or cosmetic that is falsely advertised or to deliver or proffer for delivery any such food, drug, device, or cosmetic.

110403. It is unlawful for any person to advertise any drug or device represented to have any effect in any of the following conditions, disorders, or diseases:

(a) Appendicitis.
(b) Blood disorders.
(c) Bone or joint diseases.
(d) Kidney disease or disorders.
(e) Cancer.
(f) Carbuncles.
(g) Disease, disorder, or condition of the eye.
(h) Diabetes.
(i) Diphtheria.
(j) Gall bladder disease or disorder.
(k) Heart and vascular diseases.
(l) High blood pressure.
(m) Diseases or disorders of the ear or auditory apparatus, including hearing loss and deafness.

(n) Measles.
(o) Meningitis.
(p) Mental disease or mental retardation.
(q) Paralysis.
(r) Pneumonia.
(s) Poliomyelitis.
(t) Prostate gland disorders.
(u) Conditions of the scalp, affecting hair loss, or baldness.
(v) Alcoholism.
(w) Periodontal diseases.
(x) Epilepsy.
(y) Goiter.
(z) Endocrine disorders.
(aa) Sexual impotence.
(ab) Sinus infection.
(ac) Encephalitis.
(ad) Tumors.
(ae) Venereal disease.
(af) Tuberculosis.
(ag) Ulcers of the stomach.
(ah) Varicose ulcers.
(ai) Scarlet fever.
(aj) Typhoid fever.
(ak) Whooping cough.
(al) Acquired immune deficiency syndrome (AIDS).
(am) AIDS-related complex (ARC).
(an) Diseases, disorders, or conditions of the immune system.

110405. An advertisement that is not unlawful under Section 110390 is not unlawful under Section 110403 if it is disseminated only to members of the medical, dental, pharmaceutical, or veterinary professions, or appears only in the scientific periodicals of these professions, or is disseminated only for the purpose of public health education by persons not commercially interested, directly or indirectly, in the sale of drugs or devices.

110408. Whenever the department determines that an advance in medical science has made any type of self-medication safe and effective as to any of the conditions, disorders, or diseases named in Section 110403, the department shall, by regulation, authorize the advertisement of any such drug or device as having a curative or therapeutic effect for the disease, subject to conditions and restrictions as the department may consider necessary to the interests of public health.

110410. Section 110403 shall not be construed as indicating that self-medication for conditions, disorders, or diseases other than those named is safe or efficacious.

110413. No publisher, radio or television broadcast licensee, or agency or medium for the dissemination of an advertisement, except the manufacturer, packer, distributor, or seller of the food, drug, device, or cosmetic to which a false advertisement relates, shall be liable under this article for the dissemination of the false advertisement, unless he or she has refused to furnish the department with the name and address of the manufacturer, packer, distributor, seller, or advertising agency, residing in this state who caused him or her to disseminate the advertisement.

110415. It shall be unlawful to advertise or otherwise represent chopped or ground beef or hamburger in violation of Section 110805.

110420. (a) Any fragrance advertising insert contained in a newspaper, magazine, mailing, or other periodically printed material shall contain only microencapsulated oils. Glue tabs or binders shall be used to prevent premature activation of the fragrance advertising insert.

"Fragrance advertising insert" means a printed piece with encapsulated fragrance applied to it that is activated by opening a flap or removing an overlying ply of paper.

Paperstocks employed in the manufacture of fragrance advertising inserts shall have a maximum porosity of 20 Sheffield units or 172 Gurley-Hill units.

(b) Any person who distributes fragrance advertising inserts in violation of this section, is guilty of an infraction and shall, if convicted, be subject to a fine of one hundred dollars ($100) for each distribution. The fine shall apply to each mass mailing or distribution, and to each mass publication of a magazine or newspaper in violation of this section. The fine shall not apply, however, to each individual letter, magazine, newspaper, or fragrance advertising insert so distributed. Section 111825 is not applicable to violations of this section.

(c) This section shall become operative on January 1, 1992.

CHAPTER 5. FOOD

ARTICLE 1. Generally

110425. Beer, that is subject to the Alcoholic Beverage Control Act, Division 9 (commencing with Section 23000) of the Business and Professions Code, shall only be subject to the provisions of this chapter that relate to adulteration and misbranding.

110430. Whenever the department finds that a class of food distributed in this state may, by reason of contamination with micro-organisms during manufacture, packing, or storage, be injurious to the health of any man or other animal that consumes it and that the injurious nature cannot be adequately determined after this food has entered commerce, the department shall adopt regulations providing for the issuance of permits to manufacturers, processors, or packers of the class of food. These permits shall establish conditions governing the manufacture, packing, or storage of the class of food for the period of time as may be necessary to protect the public health. The regulations shall prescribe a date after which no person shall introduce or deliver for introduction into commerce any food manufactured, packed, or stored by any manufacturer,

processor, or packer, unless the person holds a permit issued by the department as provided by the regulations.

110435. The department may suspend immediately, upon written or oral notice, any permit issued pursuant to Section 110430 if it is found that any of the conditions of the permit have been violated. The holder of a permit so suspended may at any time apply for reinstatement of the permit. The department shall, after prompt hearing and inspection of the establishment, reinstate the permit immediately, if it is found that adequate measures have been taken to comply with and maintain the conditions of the permit.

110440. Any authorized agent of the department shall have access to any factory or establishment that operates under permit from the department for the purpose of ascertaining whether or not the conditions of the permit are being complied with. Denial of access for such inspection shall be grounds for suspension of the permit until the access is freely given by the holder of the permit or his or her agent.

110445. Any added poisonous or deleterious substance, or any food additive, pesticide chemical, preservative, or color additive, shall be considered unsafe for use with respect to any food unless there is in effect a regulation adopted pursuant to Section 110080, 110085, or 110090, that limits the quantity and the use, or intended use, of the substance to the terms prescribed by the regulation.

110450. On or before September 1, 1985, the department shall, within the limits of available resources, prepare and submit to the Legislature a program for detecting and monitoring chemical and pesticide residues in processed foods. In preparing the program, the department shall do all of the following:

(a) Establish a list of chemical and pesticides developed from a knowledge of chemicals used in the food industry in processed foods and from the 96 pesticides on the Department of Food and Agriculture residue scan, for which analysis will be done by the department. The list shall include an explanation of why the listed chemicals and pesticides were selected. The Department of Food and Agriculture shall cooperate with the department in establishing the list required by this subdivision. In selecting the chemicals and pesticides to be placed on the list, the department shall make use of the following criteria:

(1) Chemicals that have been identified as having possible carcinogenic, reproductive, or mutagenic effects.

(2) Patterns of use in California.

(3) Quantities of use in California.

(4) Chemicals appearing as residues in processed food because of environmental persistence or resistance to degradation under conditions existing in the processing, manufacturing, milling, or shipping of processed foods sold in California.

(5) Chemicals that have the potential of chronic toxicity due to low continuous exposure.

The department may revise the list and is authorized to add or remove chemicals or pesticides based on relevant information that becomes available to it after the list has

been established and based on its experience in detecting the presence of chemical substances in processed foods under the sampling and testing program developed pursuant to subdivision (b).

(b) The department shall design a sampling and testing program that does all of the following:

(1) Samples and tests processed food products that form a significant portion of the diet of the general population, and that may contain residues of the chemical substances on the list established pursuant to subdivision (a).

(2) Provides for specific testing of individual chemicals on the list established pursuant to subdivision (a) when a chemical cannot be detected using multiresidue testing procedures and when the department determines that the chemical may be the cause of chronic health effects.

(3) Lists the foods to be sampled, the stages of processing in which the foods will be sampled, the sampling frequency, and the techniques used in sampling.

(4) A description of plans for sampling processed imported foods from other states and countries.

(c) As used in this section, "processed food" means any food chemically or physically altered from a raw agricultural commodity by chemical, mechanical, thermal, or other processes.

110455. (a) On or before July 1, 1990, the department shall commence and maintain a program for monitoring processed foods for pesticide residues, chemicals, microbes, and other contaminants. In designing the program, the department shall take into consideration any information developed pursuant to Section 110450.

(b) The department shall consult with the Department of Food and Agriculture in designing the pesticide residue component of the monitoring program, to facilitate focusing the testing in areas of greatest concern. Among the pesticides to be reviewed for possible monitoring shall be those contained in the lists of pesticides identified in Section 12535 of the Food and Agricultural Code.

(c) In the development and ongoing operation of the department's monitoring program, the department shall consider, in establishing priorities:

(1) Potential concentration effects that may occur during processing.

(2) Targeting foreign and domestic imported processed foods according to their estimated California market share.

(3) The extent to which processed foods are a part of the infant and child diet.

ARTICLE 2. Registration

110460. No person shall engage in the manufacture, packing, or holding of any processed food in this state unless the person has a valid registration from the department, except those engaged exclusively in the storing, handling, or processing of dried beans. The registration shall be valid for one calendar year from the date of issue, unless it is revoked. The registration shall not be transferable.

110461. It is unlawful for any person to manufacture, pack, or hold processed food in this state unless in a food processing facility duly registered, as provided in this part.

110462. It is unlawful for any person to willfully make a false statement or representation, or knowingly fail to disclose a fact required to be disclosed in the application for registration or renewal of registration, as provided in this article.

110465. A separate registration is required for each place of manufacture, packing, or holding.

110466. (a) Commencing January 1, 2000, the department shall use the resources provided by the registration fees assessed by this article to inspect new and registered food processing facilities to determine compliance with this part. The department shall target the inspections and adjust their scope, depth, and frequency based on the department's statewide assessment of public health risk potential. In assessing public health risk potential, the department shall consider, at a minimum, the potential and actual health risks associated with processed foods manufactured, packed, or held in this state, and the food safety practices and compliance histories of persons who manufacture, pack, or hold processed foods in this state.

(b) Commencing January 1, 2001, the department, pursuant to this chapter, shall conduct an annual inspection of each registered food processing facility and inspect each new food processing facility prior to issuing a new registration pursuant to Section 110460. This annual inspection requirement may be adjusted or waived based on an assessment of the food processing facility pursuant to subdivision (a).

(c) The department may perform one or more reinspections of each new and registered food processing facility as necessary to prevent repeated or continuing violations of this part and for the purposes of approving the issuance of a new registration. The department shall not charge a separate fee for a first reinspection. The department shall charge a fee of seventy-five dollars ($75) per hour to cover the costs of performing the second and subsequent reinspections of the same food processing facility within the same registration period.

110467. Any violation of any provision of this part or any regulation adopted pursuant to this part shall be grounds for denying a registration or for suspending or revoking a registration. Proceedings for the denial, suspension, or revocation of a registration shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code, and the department shall have all the powers granted in that chapter.

110470. A registration application provided by the department shall be completed annually and accompanied by a nonreturnable registration fee.
The fee for a new or renewal registration for a food processing facility shall be as follows:

Size of Establishment	Fee	Holding Food Only: Fee	Fee	Fee
	Through 12/31/1999	Commencing 01/01/2000	Commencing 01/01/2001	Commencing 01/01/2000 through

				12/31/2000 and ongoing. Los Angeles, Orange, San Bernardino Counties and the City of Vernon
0 - 5,000 sq. ft.	$257.85	$300	$300	$300
5,001-10,000 sq. ft.	$257.85	$350	$400	$350
Over 10,000 sq. ft.	$386.77	$500	$600	$500

Manufacturing or Packing Food:

Number of Employees	Size of Establishment	Fee Through 12/31/1999	Fee Commencing 01/01/2000	Fee Commencing 01/01/2001	Fee Commencing 01/01/2000 through 12/31/2000 and ongoing. Los Angeles, Orange, San Bernardino Counties and the City of Vernon
0-2	0-5,000 sq. ft.	$257.85	$300	$300	$300
3-5	0-5,000 sq. ft.	$257.85	$350	$400	$350
6-20	0-5,000 sq. ft.	$$386.77	$500	$600	$500
More than 20	0-5,000 sq. ft.	$515.70	$700	$900	$700
3-5	Over 5,000 sq. ft.	$257.85	$500	$600	$500
6-20	Over 5,000 sq. ft.	$515.70	$700	$900	$700
21-50	Over 5,000 sq. ft.	$644.52	$935	$1,250	$850
51-100	Over 5,000 sq. ft.	$644.52	$985	$1,350	$850
101-200	Over 5,000 sq. ft.	$644.52	$1,035	$1,450	$850
201 or more	Over 5,000 sq. ft.	$644.52	$1,085	$1,550	$850

A penalty of 1 percent per month shall be added to any registration fee not paid when due. The fee amount shall be adjusted annually pursuant to Section 100425

110472. The department, in consultation with the California Conference of Directors of Environmental Health (CCDEH), representatives of the food processing industry, representatives of the local health departments of, Los Angeles, Orange, and San Bernardino Counties, and the City of Vernon, and any other person or entity deemed appropriate by the department shall develop, implement, and evaluate the processed food program in accordance with this chapter. In developing the processed food program, consideration shall be given to all aspects of the program provided for in this chapter.

110473. Notwithstanding the requirements of Section 110470, any person who is required to be registered under this chapter and is operating the food processing facility exclusively for charitable purposes, and meets the requirements of Section 214 of the

Revenue and Taxation Code, shall not be required to submit any fees required by Section 110470.

110474. Nothing in this chapter shall relieve a person who has a valid registration to manufacture, pack, or hold processed food issued by the department from any other requirements for licensure, registration, or certification under Article 7 (commencing with Section 110810), Article 12 (commencing with Section 111070), or Part 6 (commencing with Section 111940). The registration fee due to the department under this article from a person who holds one or more licenses, registrations, or certificates issued by the department pursuant to Article 12 (commencing with Section 111070) or Chapters 5 to 10, inclusive of Part 6 (commencing with Section 112150) shall be the fee for the single highest cost license, registration, or certificate only. Cannery inspection fees collected pursuant to Section 112730 and organic processed food registration fees collected pursuant to Section 110875 shall be in addition to any registration fees that may be collected under this article.

110475. Any person registered pursuant to this article shall immediately notify the department of any change in the information reported on the registration application.

110480. The registration provisions of this article shall not apply to any person whose manufacturing, packing, or holding of processed food is limited solely to temporarily holding processed foods for up to seven days for further transport if the foods are not potentially hazardous foods, as defined in Section 110005, or to any person whose manufacturing, packing, or holding of processed food is limited solely to activities authorized by any of the following:

(a) A valid bottled water or water vending machine license issued pursuant to Article 12 (commencing with Section 111070).

(b) A valid pet food license issued pursuant to Chapter 10 (commencing with Section 113025) of Part 6.

(c) A valid permit issued pursuant to Chapter 4 (commencing with Section 113700) of Part 7 to a food facility including a food facility that manufactures, packs, or holds processed food for sale at wholesale, provided the food facility that manufactures, packs, or holds processed food for sale at wholesale does not meet any of the following conditions:

(1) Has gross annual wholesale sales of processed foods of more than 25 percent of total food sales.

(2) Sells processed foods outside the jurisdiction of the local health department.

(3) Sells processed foods that require labeling pursuant to this part.

(4) Processes or handles fresh seafood, frozen seafood held in bulk for further processing, or fresh or frozen raw shellfish.

(5) Salvages processed foods for sale other than at the retail food facility.

(d) A valid cold storage license issued pursuant to Chapter 6 (commencing with Section 112350) of Part 6.

(e) A valid cannery license issued pursuant to Chapter 8 (commencing with Section 112650) of Part 6.

(f) A valid shellfish certificate issued pursuant to Chapter 5 (commencing with Section 112150) of Part 6.

(g) A valid frozen food locker plant license issued pursuant to Chapter 7 (commencing with Section 112500) of Part 6.

(h) A valid winegrower's license or wine blender's license pursuant to Division 9 (commencing with Section 23000) of the Business and Professions Code.

(i) A valid milk products plant, margarine, imitation ice cream, imitation ice milk, or a products resembling milk products plant license, issued pursuant to Division 15 (commencing with Section 32501) of the Food and Agricultural Code.

(j) A valid permit issued by a local health department to operate a processing establishment, as defined in Section 111955, that only holds or warehouses processed food, pursuant to Article 1 (commencing with Section 111950) of Chapter 4 of Part 6, provided that all of the following conditions are met:

(1) The warehouse does not manufacture or pack processed food.

(2) The warehouse does not hold fresh seafood, frozen seafood held in bulk for further processing, or fresh or frozen raw shellfish.

(3) The warehouse is not operated as an integral part of a food processing facility required to be registered pursuant to Section 110460.

(4) The warehouse facilities are located entirely within the area under the jurisdiction of the local health department.

(5) The warehouse does not salvage food as the primary business.

(k) This section shall not be construed to limit the authority of Los Angeles, San Bernardino, and Orange Counties, or of the City of Vernon, to conduct any inspections otherwise authorized by Chapter 4 (commencing with Section 111950) of Part 6.

110485. (a) Every person who is engaged in the manufacture, packing, or holding of processed food in this state shall pay a food safety fee of one hundred dollars ($100) to the department in addition to any fees paid pursuant to Section 110470.

(b) Revenue received pursuant to this section shall be deposited in the Food Safety Fund created pursuant to Section 110050. A penalty of 10 percent per month shall be added to any food safety fee not paid when due.

(c) Upon appropriation, the food safety fees deposited in the Food Safety Fund shall be used by the department to assist in developing and implementing education and training programs related to food safety. These programs shall be developed in consultation with representatives of the food processing industry. Implementation shall include education and training in the prevention of microbial contamination.

(d) This section does not apply to companies exclusively involved in flour milling, dried bean processing, or in the drying or milling of rice, or to those individual registrants the director determines should not be assessed because substantial economic hardship would result to those registrants.

For the purposes of this subdivision, the substantial hardship exemption shall be extended only to registrants whose wholesale gross annual income from the registered business is twenty thousand dollars ($20,000) or less.

(e) This section shall remain in effect only until January 1, 2003, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2003, deletes or extends that date.

110490. (a) A laboratory that performs analyses of foods for pesticide chemical residues for other persons shall be accredited pursuant to Article 3 (commencing with Section 100825) of Chapter 4 of Part 1 of Division 101. This subdivision shall not apply to any of the following:
(1) A laboratory operated by a government agency.
(2) A laboratory not operated for commercial purposes that performs pesticide chemical residue analysis on foods for research or quality control for the internal use of the person initiating the analysis. For purposes of this section, "commercial purposes" means that the laboratory performs pesticide chemical residue analysis on the foods primarily for the purpose of making a profit.
(b) A laboratory accredited pursuant to Section 12591 of the Food and Agricultural Code shall not be required to be accredited under this section until January 1, 1992.
(c) A laboratory that performs analyses of foods for pesticide chemical residues, but that is not required by subdivision (a) to be accredited may apply for accreditation pursuant to Article 3 (commencing with Section 100825) of Chapter 4 of Part 1 of Division 101.
(d) This section shall become operative on January 1, 1991, or 60 days after the initial set of regulations adopted pursuant to Sections 100830 and 100835 becomes effective, whichever is later.
110495. (a) Every laboratory or other person which performs or which brokers or otherwise arranges for the performance of pesticide chemical analysis on food shall report to the appropriate state agency any finding of pesticide chemical residues in a food for which no chemical residue tolerance has been established or that is in excess of federal or state residue tolerances or tolerances for a pesticide suspended, banned, or otherwise not permitted by the Department of Pesticide Regulation or the Environmental Protection Agency, if the food is in the channels of trade. The report shall be made as soon as possible, and in any event, not later than 24 hours after the analyzing laboratory makes the finding. Findings on raw agricultural commodities and dairy products shall be reported to the Department of Food and Agriculture. Findings on raw agricultural commodities shall also be reported to the Department of Pesticide Regulation. Findings on all other foods shall be made to the State Department of Health Services.
(b) For the purpose of reporting findings regarding raw agricultural commodities, "in the channels of trade" means the point at which the raw agricultural commodities leave the farm, including raw agricultural commodities bound for processing up to the point that processing is initiated. For the purpose of reporting findings in processed foods, "in the channels of trade" means at the point the processed food leaves the direct control of the processor, which means either that the product is not located on the premises owned by, or under the control of, the processor or a portion of the product has been released for sale or use.

ARTICLE 3. Standard of Identity, Quality, and Fill

110505. Definitions and standards of identity, quality, and fill of container, and any amendments to the definitions and standards, adopted pursuant to the federal act in

effect on the effective date of this part, or adopted on or after that date, are the definitions and standards of identity, quality, and fill of container in this state. The department may, by regulation, establish definitions and standards of identity, quality, and fill of container for any food whether or not the definitions and standards are in accordance with the federal regulations, when in its judgment such action will promote honesty and fair dealing in the interest of consumers. This section shall not apply to wine.

110510. In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the department shall designate the optional ingredients that shall be named on the label. This section shall not apply to wine.

110515. A temporary permit which is granted by the Food and Drug Administration of the Department of Health, Education and Welfare of the United States for interstate shipment of experimental packs of food that vary from the requirements of federal definitions and standards of identity is automatically effective in this state under the provisions provided in the permit. The department shall issue a permit when no federal permit exists and when the experimental packs are to be manufactured and tested only within this state. The permit is subject to any term or condition that the department may prescribe.

110520. Definitions and standards of identity and quality for distilled spirits and their amendments adopted by the Internal Revenue Service of the Treasury Department of the United States in effect on the effective date of this part, or adopted on or after that date, are the definitions and standards of identity and quality for distilled spirits in this state. The department may, by regulation, establish definitions and standards of identity and quality for any distilled spirit whether or not the definitions and standards are in accordance with regulations adopted by the Internal Revenue Service of the Treasury Department of the United States, when in its judgment the action will promote honesty and fair dealing in the interest of the consumers.

110525. The department may, by regulation, establish definitions and standards of identity and quality for wine. Such definitions and standards may incorporate in whole or in part, the regulations adopted by the Secretary of the Treasury pursuant to the Federal Alcohol Administration Act, pertaining to the standards of identity and quality for wine. Standards of identity and quality for wine adopted pursuant to this section may differ from or be inconsistent with the standards promulgated by the Secretary of the Treasury pursuant to the Federal Alcohol Administration Act. No standard of size, type, or fill of container for any wine subject to the provisions of the Alcoholic Beverage Control Act, Division 9 (commencing with Section 23000) of the Business and Professions Code, shall be adopted, but containers of wine sold in this state shall conform to the then current standards for the containers, including standards of fill, established by the Secretary of the Treasury pursuant to the Federal Alcohol Administration Act.

ARTICLE 4. Enrichment of Food and Food Products

110530. When a definition and standard of identity for an enriched food has been established pursuant to Section
110505, only the enriched form of the food shall be sold at retail in California.

110535. The nonenriched form of a food identified and standardized pursuant to Section 110505 may be used as an ingredient of another food only if it comprises less than 25 percent of the total ingredients, or it comprises 25 percent or more of the total ingredients and vitamins and minerals have been added to make it nutritionally equivalent to the enriched form of the ingredient.

110540. The department shall conduct a study of feasible methods for the packaging and sale of food products that will afford the greatest protection to the public from the adulteration of those products. The study shall be conducted in conjunction with the Department of Food and Agriculture, as well as representatives of consumer groups and food producers and retailers.
In carrying out this study, the department shall cooperate with the federal Food and Drug Administration to avoid unnecessary duplication. The department shall also evaluate the applicability of federal recommendations on food product safety to the needs of California. The department shall complete the study and report its findings to the Legislature on or before March 1, 1984.

ARTICLE 5. Adulterated Food

110545. Any food is adulterated if it bears or contains any poisonous or deleterious substance that may render it injurious to health of man or any other animal that may consume it. The food is not considered adulterated if the substance is a naturally occurring substance and if the quantity of the substance in the food does not render it injurious to health.

110550. Any food is adulterated if it bears or contains any added poisonous or deleterious substance that is unsafe within the meaning of Section 110445.

110555. Any food is adulterated if it is, bears, or contains any food additive that is unsafe within the meaning of Section 110445. If, however, a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under this part or the Food and Agricultural Code and the raw agricultural commodity has been subject to processing, such as canning, cooking, freezing, dehydrating, or milling, the residue of a pesticide chemical remaining in or on the processed food shall not be deemed unsafe if the residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice, and the concentration of the residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity.

110560. Any food is adulterated if it consists in whole or in part of any diseased, contaminated, filthy, putrid, or decomposed substance, or if it is otherwise unfit for food.

110565. Any food is adulterated if it has been produced, prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered unwholesome, diseased, or injurious to health.

110570. Any food is adulterated if it is, in whole or in part, the product of any diseased animal, any animal that has died otherwise than by slaughter, or any animal that has been fed on the uncooked offal from a slaughterhouse.

110575. Any food is adulterated if its container is composed, in whole or in part, of any poisonous or deleterious substance that may render the contents injurious to health.

110580. Any food is adulterated if it has been intentionally subjected to ionizing radiation unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to Section 110070.

110585. Any food is adulterated if any one of the following conditions exist:

(a) If any valuable constituent has been in whole or in part omitted or abstracted therefrom.

(b) If any substance has been substituted wholly or in part therefor.

(c) If damage or inferiority has been concealed in any manner.

(d) If any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight or reduce its quality or strength or make it appear better or of greater value than it is.

110590. Any food is adulterated if it is confectionery and any one of the following conditions exist:

(a) It has partially or completely embedded therein any nonnutritive object, provided that this subdivision shall not apply in the case of any nonnutritive object if, in the judgment of the department as provided by regulation, the object is of practical functional value to the confectionery product and would not render the product injurious or hazardous to health.

(b) It bears or contains any alcohol in excess of 5 percent by weight.

(c) It bears or contains any nonnutritive substance, provided that this subdivision shall not apply to a safe nonnutritive substance that is in or on confectionery by reason of its use for some practical functional purpose in the manufacture, packaging, or storage of the confectionery if the use of the substance does not promote deception of the consumer or otherwise result in adulteration or misbranding in violation of any provision of this act; and provided further that the department may, for the purpose of avoiding or resolving uncertainty as to the application of this clause, issue regulations allowing or prohibiting the use of particular nonnutritive substances.

110595. Any food is adulterated if it bears or contains any color additive that is unsafe within the meaning of Section 110445.

110600. Any food is adulterated if it is fresh meat and it contains any preservative or other chemical substance not approved for use in fresh meat by the department, the United States Department of Agriculture, or the Department of Food and Agriculture of this state.

110605. Any food is adulterated if it is chopped or ground beef or hamburger unless it is composed of voluntary striated muscle of fresh beef that does not contain any substance that is not approved by the department and unless it has a total fat content that is not in excess of 30 percent by weight.

110610. Any food is adulterated if it is pork sausage or breakfast sausage and it has a total fat content that is in excess of 50 percent by weight.

110615. The methods of analysis used in determining the fat content of products described in Sections 110605 and 110610 shall be those prescribed by the current issue of "Official and Tentative Methods of Analysis of the Association of Official Analytical Chemists," and the supplements thereto.

110620. It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any food that is adulterated.

110625. It is unlawful for any person to adulterate any food.

110630. It is unlawful for any person to receive in commerce any food that is adulterated or to deliver or proffer for delivery any such food.

110635. While any regulation relating to a substance referred to in Section 110080, 110085, or 110090 is in effect, any food bearing or containing a substance in accordance with the regulation shall not be considered to be adulterated.

110640. The director, with the assistance of the Department of Food and Agriculture, and in cooperation with the federal Food and Drug Administration and Environmental Protection Agency, shall identify those pesticides most likely to leave residue in processed foods.

110645. Whenever the director has been notified by the Director of Food and Agriculture pursuant to Section 12582 of the Food and Agricultural Code, the director shall immediately notify the processor, if known, by telephone, with immediate written confirmation, and take appropriate action pursuant to Section 110045.

110650. This article does not prohibit the addition of fluorine or fluorine compounds to water intended for sale to the public as bottled water for domestic use in the manner and to the extent as may be approved by the department. The label of the bottled water shall, however, satisfy all of the labeling requirements prescribed by this part.

110655. Any food intended for export shall not be deemed to be adulterated within the provisions of this part if it satisfies all of the following requirements:

(a) It accords to the specifications of the foreign purchaser.

(b) It is not in conflict with the laws of the importing country.

(c) It is labeled on the outside of the shipping package to show that it is intended for export.

If the article is sold or offered for sale in domestic commerce, this section shall not exempt it from any of the provisions of this part.

ARTICLE 6. Misbranded Food

110660. Any food is misbranded if its labeling is false or misleading in any particular.

110661. Any food is misbranded if it is manufactured, packed, or held in this state in a food processing facility not duly registered as provided in this part, except for food from facilities exclusively storing, handling, or processing dry beans.

110665. Any food is misbranded if its labeling does not conform with the requirements for nutrition labeling as set forth in Section 403(q) (21 U.S.C. Sec. 343(q)) of the federal act and the regulations adopted pursuant thereto. Any food exempted from those requirements under the federal act shall also be exempt under this section.

110670. Any food is misbranded if its labeling does not conform with the requirements for nutrient content or health claims as set forth in Section 403(r) (21 U.S.C. Sec. 343(r)) of the federal act and the regulations adopted pursuant thereto. Any food exempted from those requirements under the federal act shall also be exempt under this section.

110675. Any food is misbranded if it is in package form, unless it bears a label containing all of the following information:

(a) The name and place of business of the manufacturer, packer, or distributor.

(b) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count.

Reasonable variations from the requirements of subdivision (b) shall be permitted. Requirements for placement and prominence of the information required by subdivision (b), and exemptions as to small packages, shall be established in accordance with regulations adopted pursuant to Sections 110100 and 110380.

110680. Any food is misbranded if its labeling or packaging does not conform to the requirements of Chapter 4 (commencing with Section 110290).

110685. Any food is misbranded if it is offered for sale under the name of another food, or if it is an imitation of another food for which a definition and standard of identity has been established by regulation and its label does not bear, in type of uniform size and prominence the word "imitation," and immediately following, the name of the food imitated.

110690. Any food is misbranded if its container is so made, formed, or filled as to be misleading.

110695. Any food is misbranded if it is a confectionery and contains alcohol in excess of 12 of 1 percent by weight and that fact does not appear on the label for the food.

110700. Any food is misbranded if it is a potentially hazardous processed food that is preserved by refrigeration at temperatures of 45 degrees Fahrenheit or lower and it is not conspicuously labeled "Perishable Keep Refrigerated."

110705. Any food is misbranded if any word, statement, or other information required pursuant to this part to appear on the label or labeling is not prominently placed upon the label or labeling with conspicuousness, as compared with other words, statements, designs, or devices in the labeling and in terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

110710. Any food is misbranded if it purports to be, or is represented as, a food for which a definition and standard of identity has been established under Section 110505 and the label fails to bear the name of the food specified in the standard or otherwise fails to conform to the definition and standard.

110715. Any food is misbranded if it purports to be, or is represented as, a food for which a standard of quality or fill has been prescribed by regulation under Section 110505 and its quality or fill is below the standard unless its label bears, in a manner and form as specified by regulation, a statement that it is below the standard.

110720. Any food for which no standard of identity exists is misbranded unless it bears a label clearly stating the common or usual name of the food.

110725. (a) Any food fabricated from two or more ingredients is misbranded unless it bears a label clearly stating the common or usual name of each ingredient, and if the food purports to be a beverage containing vegetable or fruit juice, a statement with appropriate prominence on the information panel of the total percentage of fruit or vegetable juice contained in the food. Any spice, flavoring, or color not required to be certified under Section 110090, except any spice, flavoring, or color sold as such, may be designated as spice, flavoring, or color without naming each.

(b) Exemptions may be established by the department, when compliance with any requirement of this section is impractical or results in deception or unfair competition.

(c) In adopting any regulations relating to this section, the department shall take into consideration the current regulations established by the Secretary of Health and Human Services under authority contained in the federal act.

(d) Notwithstanding Section 110040 or any other provision of law, as used in this section, the term "food" includes, but is not limited to, meat. The term "food" does not, however, include any alcoholic beverage.

(e) This section shall not apply to any food sold for consumption on or off the premises of any restaurant in the course of its business as a restaurant, or to any milk or dairy product.

110730. The requirements of Sections 110720 and 110725 do not apply to any food that is packaged at the direction of retail purchasers at the time of sale if the ingredients are disclosed to the purchasers by other means in accordance with the regulations adopted by the department.

110735. Any food is misbranded if it purports to be, or is represented, for special dietary uses as prescribed by regulation under Section 110095 and its label does not bear information concerning any vitamin or mineral content, or other dietary property as the department prescribes, by regulation, as necessary to fully inform purchasers as to the food's value for that use.

110740. Any food is misbranded if it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless its labeling states that fact. Exemptions may be established by the department.

110745. Any food is misbranded if it is intended as a component of another food and when used in accordance with the directions of the purveyor, it will result in the final food being adulterated or misbranded.

110750. Any food is misbranded if it is a color additive and it is not in conformity with the requirements for color additives prescribed under the provisions of Section 110090.

110755. Any food is misbranded if its packaging or labeling is in violation of an applicable regulation issued pursuant to Section 108685 or 108700.

110760. It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any food that is misbranded.

110765. It is unlawful for any person to misbrand any food.

110770. It is unlawful for any person to receive in commerce any food that is misbranded or to deliver or proffer for delivery any such food.

110775. It is unlawful for any person to alter, mutilate, destroy, obliterate, or remove the label, or any part of the labeling, of any food if the act results in the food being misbranded.

110780. It is unlawful for any person to manufacture, pack, or hold processed food in this state unless in an establishment duly registered, as provided in this part.

110790. Any food intended for export shall not be deemed to be misbranded under this part if it satisfies all of the following requirements:

(a) It accords to the specifications of the foreign purchaser.

(b) It is not in conflict with the laws of the importing country.

(c) It is labeled on the outside of the shipping package to show that it is intended for export.

If the article is sold or offered for sale in domestic commerce, this section shall not exempt it from any of the provisions of this part.

110795. (a) The department may adopt regulations that name and describe the characteristics of salmon and any other fish or other seafood it considers appropriate. The department shall consult with the Department of Fish and Game, the Joint Committee on Fisheries and Aquaculture, consumers, commercial fishermen, aquaculturists, and seafood processors, wholesalers, restaurateurs, and other retailers before adopting these regulations. The department shall not adopt any regulation that conflicts with the common name of any fish designated by the Department of Fish and Game pursuant to Section 8023 of the Fish and Game Code.

(b) In addition to the consultations required by subdivision (a), the department shall consult and seek the recommendations of the groups named in that subdivision concerning the possible need for, or desirability of, any further legislation or regulations affecting seafood labeling. The department shall report to the Legislature the results of the consultations required by this subdivision, and make recommendations to the Legislature concerning any legislation it considers appropriate, on or before January 1, 1986.

(c) No regulation adopted pursuant to this section shall deviate from a pertinent United States standard where the fish or seafood product specified is packed or processed as a standardized product under a United States standard.

(d) Nothing in this section or in regulations adopted pursuant to this section shall be construed to require the use of more than the common family name of any fish or seafood by any restaurant in menus or advertisements.

110800. (a) Any label of any retail cut of beef, veal, lamb, or pork held for sale in a retail food production and marketing establishment or a frozen food locker plant shall clearly identify the species (beef, veal, lamb, or pork) and the primal cut from which it is derived, and the retail name.

This section shall not apply to ground beef or hamburger, boneless stewing meat, cubed steaks, sausage, or soupbones.

(b) "Primal cuts" include only the following in the various species:

Beef	Veal	Lamb	Pork
Chuck	Shoulder	Shoulder	Shoulder
Rib	Rib	Rib	--
Loin	Loin	Loin	Loin
Shank	Shank	Shank	--
Brisket	Breast	Breast	--
Plate	Breast	Breast	--
Flank	Flank	--	--
Round	Round or leg	Leg	Leg or ham

Cuts derived from other than the above primal cuts need only show species and the retail name.

(c) It is unlawful and constitutes misbranding for any person to sell or offer for sale in a retail food production and marketing establishment or frozen food locker plant any retail cut of beef that is labeled in violation of this section.

110805. No chopped or ground beef or hamburger that is offered for sale in any retail food production and marketing establishment or frozen food locker plant shall be advertised, labeled, or otherwise held out in any manner to describe or suggest its quality or relative leanness or fat content unless the label, advertisement, or other representation accurately discloses the maximum fat content thereof by one of the following designations:

(a) Does not exceed 30 percent fat.

(b) Does not exceed 22 percent fat.

(c) Does not exceed 15 percent fat.

No designation such as, but not limited to, "lean," "super lean," "premium," "deluxe" or similar terms descriptive of quality, leanness, or fat content shall be included on the label unless the label also contains the fat-weight designation specified in subdivision (a), (b), or (c). However, as an alternative to including the fat-weight designation on the label, the fat-weight designation required by this section may be disclosed by means of a sign placed immediately adjacent to the counter on which the chopped or ground beef or hamburger is displayed. Such a sign shall be within plain view of prospective purchasers and shall display the appropriate designation specified in subdivision (a), (b), or (c) in boldface print.

Chopped or ground beef or hamburger that is processed from primal cuts of round or sirloin shall not be required to disclose the maximum fat content if there is no reference to leanness or other quality designation relating to fat content other than the primal cut from which the product is derived; provided, in the case of ground beef or hamburger processed from the primal cut of chuck when the primal cut designated is being used, the fat content of the chopped ground beef or hamburger shall not exceed 26 percent.

All labeling and advertising for chopped or ground beef or hamburger processed from the primal cut chuck shall disclose the maximum fat weight designated as, "Does not exceed 26 percent fat."

It is unlawful and constitutes misbranding for any person to sell or offer for sale in a retail food production and marketing establishment or frozen food locker plant any chopped or ground beef or hamburger that is labeled in violation of this section.

ARTICLE 7. The California Organic Foods Act of 1990

110810. This article shall be known, and may be cited as, the California Organic Foods Act of 1990.

110815. The following words and phrases, when used in this article, shall have the following meanings:

(a) "Administered" means ingested, injected, or otherwise topically or internally introduced to livestock, fowl, or fish.

(b) "Applied" means introduced, incorporated within, added to, or placed upon any seed, crop, plant, livestock, fowl, fish, soil, or growing medium, and shall also mean used in, on, or around any facility or area in which food is kept.

(c) "Area" means the physical space surrounding food where there is more than a negligible chance of a prohibited material being absorbed by, incorporated into, or adhered to the food, soil, or growing medium. The area may differ significantly depending on the circumstances. Except in the case of the production of food, area shall not include any physical space surrounding food if an intervening event, such as the use of a cleaning method for processing equipment, or the passage of time, has made the chance of a prohibited material being absorbed by, incorporated into, or adhered to the food, negligible.

(d) "Botanicals" means substances derived solely from plants or plant parts.

(e) "Endemic disease" means a disease in animal or fish that is either universal or common to a species within the geographic region.

(f) "Enforcement authority" means the governmental unit with primary enforcement jurisdiction, as provided in Section 110925.

(g) "Field" means a contiguous area of land for agricultural production that is managed with a consistent set of production methods.

(h) "Feed" means any substance used or intended for consumption by livestock, fowl, or fish to provide nourishment, including range and pasturage vegetation.

(i) "Growing medium" means a substance that provides nutrients for plants or fungi but which is separate from the land surface of the world.

(j) "Handled" means shipped, packed, repacked, sold for resale, warehoused, wholesaled, imported into the state, or stored by other than a grower, producer, processor, or retailer of that food.

(k) "Management unit" means the physical facilities and equipment associated with crop production that is not confined to a field, such as animal production, greenhouse production, or seed sprouting. Management units shall be described by the location and function of the physical facilities and equipment, and other aspects as determined by the enforcement authority. In the case of animal production, the management units shall also be described by the quantity and source of each group of animals that is managed together as a unit.

(l) "Processed" means cooking, baking, heating, drying, mixing, grinding, crushing, pressing, churning, separating, extracting juices or other materials, peeling, fermenting, eviscerating, preserving, dehydrating, freezing, or manufacturing that materially alters the flavor, keeping quality, or any other property, or the making of any substantial change of form. "Processed" does not include refrigeration at temperatures that are above the freezing point nor any other treatment that merely retards or accelerates the natural processes of ripening or decomposition.

(m) "Produced" means grown, raised, harvested, handled, or stored under the control of the grower or producer.

(n) "Producer," "handler," and "processor" means any person who has, respectively, produced, handled, or processed any food.

(o) "Production," "handling," and "processing" means the process by which any food is, respectively, produced, handled, and processed.

(p) "Prohibited materials" means any of the following:

(1) When used in connection with the production, handling, or processing of meat, fowl, or fish:

(A) Any drug, medication, hormone or growth regulator, whether or not synthetic, or any other synthetic substance, including, but not limited to, any substance administered to stimulate or regulate growth or tenderness, and any subtherapeutic dose of antibiotic. The use of a drug or medication for medical treatment of a specific and manifest malady diagnosed and prescribed by a licensed veterinarian, or under the general supervision of a licensed veterinarian, shall be permitted, but not within 90 days prior to slaughter or twice the withdrawal time specified by the federal Food and Drug Administration, whichever is longer. In addition, vaccines may be administered for prevention of an endemic disease or as required by law. Vitamin and mineral supplements also may be administered.

(B) Any feed administered to livestock, fowl, or fish that does not comply with the requirements of regulations adopted pursuant to Section 14904 of the Food and Agricultural Code.

(C) Any artificial rumen stimulants, such as plastic pellets.

(D) Any manure intentionally fed or refed.

(E) Any synthetically compounded substance applied postslaughter to the meat, fowl, or fish itself, or to its packaging, including preservatives.

(F) Any substance applied to any area where livestock, fowl, or fish or meat, fowl, or fish products are handled or kept at any time that does not consist entirely of microorganisms, microbiological products, or substances consisting of, or derived or extracted solely from, plant, animal, or mineral-bearing rock substances. Prohibited materials shall not include the application of botanicals, lime-sulfur, gypsum, soaps, and detergents. Prohibited materials shall include the application of petroleum solvents, diesel, and other petroleum fractions.

(2) When used in connection with the production, distribution, or processing of dairy products or eggs:

(A) Any drug, medication, hormone, or growth regulator, whether or not synthetic, and any other synthetic substance, including, but not limited to, any substance administered to stimulate or regulate growth, milk or egg production, and any subtherapeutic dose of antibiotic. The use of a drug or medication for medical treatment of a specific and manifest malady diagnosed and prescribed by a licensed veterinarian, or under the general supervision of a licensed veterinarian, shall be permitted, but not less than 30 days prior to taking of the milk or laying of eggs, or twice the withdrawal time specified by the federal Food and Drug Administration, whichever is longer. In addition, vaccines may be administered for prevention of an endemic disease or as required by law. Vitamin and mineral supplements may also be administered.

(B) Any feed administered to livestock within one year of the taking of the milk, or to fowl within six months of the laying of eggs, that does not comply with the

requirements of regulations adopted pursuant to Section 14904 of the Food and Agricultural Code.

(C) Any artificial rumen stimulants, such as plastic pellets.

(D) Any manure intentionally fed or refed.

(E) Any substance applied to any area where livestock, fowl, or fish, or meat, dairy, fowl, or fish products are handled or kept at any time that does not consist entirely of micro-organisms, microbiological products, or substances consisting of, or derived or extracted solely from, plant, animal, or mineral-bearing rock substances. Prohibited materials shall not include the application of botanicals, lime-sulfur, gypsum, soaps, and detergents. Prohibited materials shall include the application of petroleum solvents, diesel, and other petroleum fractions.

(3) When used in connection with the production, handling, or processing of raw agricultural commodities and any other food not specified in paragraphs (1) and (2), any synthetically compounded fertilizer, pesticide, growth regulator, or any other substance that does not consist entirely of micro-organisms, microbiological products, or substances consisting of, or derived or extracted solely from plant, animal, or mineral-bearing rock substances. Before harvest, prohibited materials shall not include the application of bordeaux mixes and trace elements for known deficiencies as determined by plant or animal tissue or by soil testing, soluble aquatic plant products, botanicals, lime-sulfur, gypsum, dormant oils, summer oils, fish emulsion, soaps, and detergents, except for petroleum solvents, diesel, and other petroleum fractions, used as weed or carrot oils. Prohibited materials shall not include the application of soaps and detergents.

(4) Water, including substances dissolved in water, shall not be a prohibited material, even if it contains incidental contamination from a prohibited material, if the prohibited material was not added by, or under the direction or control of, the producer, handler, processor or retailer.

(q) "Retailer" means a person engaged in the sale to consumers of food sold as organic and not engaged in the production, handling or processing of food sold as organic.

(r) "Sold as organic" means any use of the terms "organic," "organically grown," "naturally grown," "ecologically grown," or "biologically grown," or grammatical variations of those terms, whether orally or in writing, in connection with any food grown, handled, processed, sold, or offered for sale in this state, including, but not limited to, any use of these terms in labeling or advertising of any food and any ingredient in a multi-ingredient food, except as provided in Section 110880.

(s) "Substance" includes all components of a substance, including active and inert ingredients.

(t) "Synthetically compounded" means formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources, excepting microbiological processes.

110820. Except as otherwise provided in this article, no food shall be sold as organic unless it consists entirely of any of the following:

(a) Raw agricultural commodities that meet the following requirements:

(1) The commodity has been produced and handled without any prohibited material or color additive having been applied, and without irradiation.

(2) In the case of any raw agricultural commodity produced from seed, the seed has not been treated with any prohibited material. If untreated seed is not available, seed treated with a fungicide may be used, except for seed used for sprouts and other raw agricultural commodities, as described in paragraph (6).

(3) In the case of perennial crops:

For fields or management units registered with the county agricultural commissioner pursuant to Section 46002 of the Food and Agricultural Code commencing January 1, 1996, no prohibited material shall have been applied to the crop, field, management unit, or area where the commodity is grown for 36 months prior to harvest.

(4) In the case of annual or two-year crops:

For fields or management units registered with the county agricultural commissioner pursuant to Section 46002 of the Food and Agricultural Code commencing January 1, 1996, no prohibited material shall have been applied to the crop, field, management unit, or area where the commodity is grown for 36 months prior to harvest.

(5) In the case of any raw agricultural commodity that is grown in any growing medium, such as fungi grown in compost or transplants grown in potting mix:

(A) The growing medium must have been manufactured or produced:

(i) Without any prohibited material having been included in the medium.

(ii) Without any prohibited material having been applied to the area where the medium is manufactured or produced during seeding or inoculation of the medium.

(iii) Using methods that will minimize the migration or accumulation of any pesticide chemical residue in food grown in the medium.

(B) No prohibited material shall have been applied to the area where the commodity is grown during seeding or inoculation.

If a prohibited material is applied in the area prior to seeding or inoculation, a residue test shall be performed on the commodity grown from that seeding or inoculation.

(6) In the case of sprouts and other raw agricultural commodities as described in subparagraph (B):

(A) The seed shall have been organically produced, handled, and processed in accordance with this article. No prohibited material shall have been applied to the seed or to the area in which the commodity is grown after introduction of the seed.

(B) This paragraph and the requirements of paragraphs (4) and (5), where applicable, shall apply to raw agricultural commodities that are grown directly from seed through either of the following methods:

(i) Without soil or growing medium other than water.

(ii) On a soil or growing medium and seeded at a rate greater than one ounce per square foot (2,722 pounds per acre).

(b) Processed food manufactured only from raw agricultural commodities as described in subdivision (a), except as follows:

(1) Water, air, and salt may be added to the processed food.

(2) Ingredients other than raw agricultural commodities as described in subdivision (a) may be added to the processed food if these ingredients are included in

the California administrative list of materials approved for organic food processing or the national list adopted by the United States Secretary of Agriculture pursuant to Section 6517 of the federal Organic Foods Production Act (7 U.S.C. Sec. 6501 et seq.) and do not represent more than 5 percent of the weight of the total finished product, excluding salt and water.

(c) Processed food manufactured only from a combination of raw agricultural commodities as described in subdivision (a) and processed food as described in subdivision (b).

(d) (1) Meat, fowl, fish, dairy products, or eggs that are produced, distributed, and processed without any prohibited material having been applied or administered, except as provided in paragraph (2) with respect to dairy products.

(2) For the first 10 months of the year prior to the taking of the milk, 80 percent of any feed administered to dairy livestock shall be comprised of materials in compliance with the regulations adopted pursuant to Section 14904 of the Food and Agricultural Code. For the final two-month period prior to the taking of the milk, 100 percent of any feed administered to the dairy livestock shall be in compliance with the regulations adopted pursuant to Section 14904 of the Food and Agricultural Code.

110825. No food that contains any prohibited material residue as a result of spray drift or any other contamination beyond the control of the producer, handler, processor, or retailer, may be sold as organic unless the amount of residue does not exceed 5 percent of the federal Environmental Protection Agency tolerance level.

110830. (a) No food grown, handled, processed, sold, advertised, represented, or offered for sale in this state, shall be sold as organic unless it also is prominently labeled, invoiced, and represented as follows, or with substantially similar language:

(1) For raw agricultural commodities:

ORGANICALLY GROWN IN ACCORDANCE WITH THE CALIFORNIA ORGANIC FOODS ACT OF 1990.

(2) For processed food:

ORGANICALLY GROWN AND PROCESSED IN ACCORDANCE WITH THE CALIFORNIA ORGANIC FOODS ACT OF 1990.

(3) For unprocessed meat, fowl, fish, dairy products, or eggs:

ORGANICALLY PRODUCED IN ACCORDANCE WITH THE CALIFORNIA ORGANIC FOODS ACT OF 1990.

(b) For unpackaged food sold as organic to consumers, physical attachment to the food of the applicable language set forth in subdivision (a) shall not be required if the language appears prominently on or near the bin or container holding the food.

(c) For food certified by a registered certification organization in accordance with Sections 110850 to 110870, inclusive, or Section 46009 of the Food and Agricultural Code, the term "CERTIFIED" may be used in labeling food sold as organic by the producer and by any handler if the name of the registered certification organization precedes or follows that term in the same size type, and if subdivisions (a) and (b) have been met.

(d) When unprocessed food that has been certified by two or more registered certification organizations, is commingled by a handler or retailer, but is not processed,

the food shall thereafter be labeled as set forth in paragraph (1) or (3) of subdivision (a), and subdivisions (b) and (c), with the name of each certification organization that has certified any of the food.

(e) Except as provided in subdivision (f), when less than all of the ingredients in a multi-ingredient food are produced, handled, and, if applicable, processed in accordance with Section 110820, the food shall not be sold as organic. However, those ingredients produced, handled, and processed in accordance with Section 110820 may be described using the terms contained in subdivision (r) of Section 110815 on the principal display panel of the food if the terms are clearly used only to modify those ingredients and only if 100 percent of those ingredients are produced in accordance with Section 110820. The use of the terms shall be limited to no greater than three-quarters of the type size of the statement of identity.

Additionally or alternatively, those ingredients produced, handled, and processed in accordance with Section 110820 may be described using the terms contained in subdivision (r) of Section 110815 on the ingredient list on the packaging, if all other provisions of this article are met.

(f) No food may be advertised or labeled as "organic when available" or similar terminology that leaves in doubt whether the food is being sold as organic.

(g) The provisions of this article relating to the labeling of meat and meat products and poultry and poultry products shall not be interpreted to authorize any labeling of those products, that is subject to the jurisdiction of federal labeling laws, in a manner inconsistent with those federal labeling laws.

(h) Notwithstanding subdivision (a), until January 1, 1992, any person may utilize existing supplies of labels that conform to the requirements of former Section 26569.13.

110835. The director may adopt regulations or administrative lists of specific substances that are in compliance or not in compliance with subdivision (p) of Section 110815 for use in the processing of foods under the enforcement jurisdiction of the department.

110840. (a) All persons who produce raw agricultural commodities that are sold as organic shall keep accurate and specific records of the following:

(1) For each field or management unit, all substances applied to the crop, soil, growing medium, growing area, irrigation or postharvest wash or rinse water, or seed, including all substances applied during the time periods specified in paragraphs (3) to (6), inclusive, of subdivision (a) of Section 110820, the quantity of each substance applied, and the date of each application. All substances shall be identified by brand name, if any, and by source.

(2) The quantity harvested from each field or management unit, the size of the field or management unit, the field number, and the date of harvest.

(3) The name and address and, if applicable, the registration numbers issued pursuant to Section 110875 of this code or Section 46002 of the Food and Agricultural Code of all handlers, processors, or retailers to whom the food is sold or otherwise transferred, the quantity of food sold or otherwise transferred, and the date of the transaction.

(b) All persons who produce meat, fowl, fish, dairy products, or eggs sold as organic shall keep accurate and specific records of the following:

(1) Unless the livestock, fowl, or fish was raised or hatched by the producer, the name and address and, if applicable, the registration numbers issued pursuant to Section 110875 of this code or Section 46002 of the Food and Agricultural Code of all suppliers of livestock, fowl, or fish and the date of the transaction.

(2) The name and address and, if applicable, the registration numbers issued pursuant to Section 110875 of this code or Section 46002 of the Food and Agricultural Code of all suppliers of feed, the quantity of feed purchased, and the date of the transaction.

(3) All substances administered and fed to the animal, including all feed, medication and drugs, and all substances applied in any area in which the animal, milk, or eggs are kept, including the quantity administered or applied, and the date of each application. All substances shall be identified by brand name, if any, and by source.

(4) The name and address and, if applicable, the registration numbers issued pursuant to Section 110875 of this code or Section 46002 of the Food and Agricultural Code of all handlers, processors, or retailers to whom the food is sold or otherwise transferred, the quantity of food sold or otherwise transferred, and the date of the transaction.

(c) All persons who handle food sold as organic shall keep accurate and specific records of the following:

(1) The name and address and, if applicable, the registration numbers issued pursuant to Section 110875 of this code or Section 46002 of the Food and Agricultural Code of all suppliers of the food, the quantity of food purchased or otherwise transferred, and the date of the transaction.

(2) Invoices for each shipment from the supplier that state that the food may be sold as organic.

(3) If the food is labeled or represented to be certified, invoices from the supplier or separate written documentation from a certification organization that states that the food is certified under this article.

(4) All pesticide chemicals applied to the food while in the control of the handler, including the quantity applied, and the date of each application. All pesticide chemicals shall be identified by brand name, if any, and by source.

(5) All substances routinely applied in or around any area or container in which the food is kept. All substances shall be identified by brand name, if any, and by source. This record may be provided in the form of a single list of substances used.

(6) The name and address and, if applicable, the registration numbers issued pursuant to Section 110875 of this code or Section 46002 of the Food and Agricultural Code of all persons to whom the food is sold or otherwise transferred, the quantity of food sold or otherwise transferred, and the date of the transaction.

(d) All persons who process food sold as organic shall keep accurate and specific records of the following:

(1) The name and address and, if applicable, the registration numbers issued pursuant to Section 110875 of this code or Section 46002 of the Food and Agricultural Code of all suppliers of the food, the quantity of food purchased or otherwise transferred, and the date of the transaction.

(2) Invoices for each shipment from the supplier that state that the food may be sold as organic.

(3) If the food is labeled or represented to be certified, invoices from the supplier or separate written documentation from a certification organization that states that the food is certified under this article.

(4) All substances applied to the food or used in its processing, all substances applied to the food while in the control of the processor, and all substances applied in or around any area or container in which the food is kept, including the quantity of substances applied and the date of each application. All substances shall be identified by brand name, if any, and by source.

(5) The name and address and, if applicable, the registration numbers issued pursuant to Section 110875 of this code or Section 46002 of the Food and Agricultural Code of all handlers, processors, or retailers to whom the food is sold or otherwise transferred, the quantity of food sold or otherwise transferred, and the date of the transaction.

(e) All persons who sell, at retail, food sold as organic shall keep accurate and specific records of the following:

(1) The name and address and, if applicable, the registration numbers issued pursuant to Section 110875 of this code or Section 46002 of the Food and Agricultural Code of all suppliers of the food, the quantity of food purchased or otherwise transferred, and the date of the transaction.

(2) Invoices for each shipment from the supplier that state that the food may be sold as organic.

(3) If the food is labeled or represented to be certified, invoices from the supplier or separate written documentation from a certification organization that states that the food is certified under this article.

(4) All pesticide chemicals applied to the food while in the control of retailer, including the quantity applied, and the date of each application. All pesticide chemicals shall be identified by brand name, if any, and by source.

(5) All substances routinely applied in or around any area or container in which the food is kept. All substances shall be identified by brand name, if any, and by source. This record may be provided in the form of a single list of substances used. One list may be kept at the retailer's headquarters office if all individual stores operated by that retailer utilize only the substances on the list.

Paragraphs (1) and (2) shall not apply to a person who both produces and sells, at retail, the same food. The records required to be kept pursuant to paragraphs (1) to (4), inclusive, of this subdivision may be kept at the retailer's warehouse or headquarters office.

(f) All records required to be kept under this section shall be maintained by producers for not less than three years and by handlers and processors for not less than two years from the date that the food is sold, and shall be maintained by retailers for not less than one year from the date that the food is received by the retailer. These records shall be made available for inspection at any time by the director or the Director of Food and Agriculture and by each certification organization that certifies the food, if any, for purposes of carrying out this article and Chapter 10 (commencing with Section 46000) of Division 17 of the Food and Agricultural Code.

110845. (a) Notwithstanding any other provision of law, any producer, handler, processor, or retailer of food sold as organic shall immediately make available for inspection by, and shall upon request, within 72 hours of the request, provide a copy to, the director, the Attorney General, any prosecuting attorney, any governmental agency responsible for enforcing laws related to the production or handling of food sold as organic, or the Secretary of Food and Agriculture of any record required to be kept under this section for purposes of carrying out this article and Chapter 10 (commencing with Section 46000) of Division 17 of the Food and Agricultural Code. Records acquired pursuant to this subdivision shall not be public records as that term is defined in Section 6252 of the Government Code and shall not be subject to Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code.

b) Upon written request of any person that establishes cause for the request, the director and the Secretary of Food and Agriculture shall obtain and provide to the requesting party within 10 working days of the request a copy of any of the following records required to be kept under this article that pertain to a specific product sold or offered for sale, and that identify substances applied, administered, or added to that product, except that financial information about an operation or transaction, information regarding the quantity of a substance administered or applied, the date of each administration or application, information regarding the identity of suppliers or customers, and the quantity or price of supplies purchased or products sold shall be removed before disclosure and shall not be released to any person other than persons and agencies authorized to acquire records under subdivision (a):

(1) Records of a producer, as described in paragraph (1) of subdivision (a) and in paragraph (3) of subdivision (b) of Section 110840.

(2) Records of a handler, as described in paragraphs (4) and (5) of subdivision (c) of Section 110840, records of previous handlers, if any, and producers as described in paragraph (1) of subdivision (a) of, paragraph (3) of subdivision (b) of, and paragraphs (4) and (5) of subdivision (c) of, 110840, without identifying the previous handlers or producers, and, if applicable, records obtained as required in subdivision (d).

(3) Records of a processor, as described in paragraph (4) of subdivision (d) of Section 110840, except for processing aids that are not residual in the product and spices and seasonings exempt from labeling requirements in Parts 145 and 146 of Title 21 of the Code of Federal Regulation, records of previous processors and handlers, if any, and producers as described in paragraph (1) of subdivision (a) of, paragraph (3) of subdivision (b) of, paragraphs (4) and (5) of subdivision (c) of, and paragraph (4) of subdivision (d) of, Section 110840, without identifying the previous processors, handlers, or producers, and, if applicable, records obtained as required in subdivision (d).

(4) Records of a retailer, as described in paragraphs (4) and (5) of subdivision (e) of Section 110840, records of previous processors and handlers, if any, and producers as described in paragraph (1) of subdivision (a) of, paragraph (3) of subdivision (b) of, paragraphs (4) and (5) of subdivision (c), and paragraph (4) of subdivision (d) of, Section 110840, without identifying the previous processors, handlers, or producers, and, if applicable, records obtained as required in subdivision (d).

This subdivision shall be the exclusive means of public access to records required to be kept by producers, processors, handlers, and retailers under this article.

A person required to provide records pursuant to a request under this subdivision, may petition the director or the Secretary of Food and Agriculture to deny the request based on a finding that the request is of a frivolous or harassing nature. The secretary or director may, upon the issuance of such a finding, waive the information production requirements of this subdivision for the specific request for information that was the subject of the petition.

(c) Information specified in subdivision (b) that is required to be released upon request shall not be considered a "trade secret" under Section 110165, Section 1060 of the Evidence Code, or the Uniform Trade Secrets Act (Title 5 (commencing with Section 3426) of Part 1 of Division 4 of the Civil Code).

(d) The director or the Secretary of Food and Agriculture may charge the person requesting records a reasonable fee to reimburse him or her self or the source of the records for the cost of reproducing the records requested.

(e) Any person who first imports into this state, for resale, food sold as organic shall obtain and provide to the enforcement authority, upon request, proof that the products being sold have been certified by an accredited certifying organization or have otherwise been produced in compliance with this article.

(f) The director shall not be required to obtain records not in his or her possession in response to a subpoena. Prior to releasing records required to be kept pursuant to this chapter in response to a subpoena, the director shall delete any information regarding the identity of suppliers or customers and the quantity or price of supplies purchased or products sold.

110850. (a) Commencing January 1, 1996, all organic products shall be certified by a registered certifying organization, and food shall be sold as organic only in accordance with this section, subdivisions (c) and (d) of Section 110830, Sections 110855 to 110870, inclusive, and Section 46009 of the Food and Agricultural Code. The Secretary of Food and Agriculture, director, and the county agricultural commissioners shall carry out this subdivision to the extent that adequate funds are made available for that purpose.

(b) Food sold as organic may be certified only by a certification organization registered pursuant to subdivisions (c) and (d), by the director pursuant to subdivision (f), by a certification organization registered pursuant to Section 46009 of the Food and Agricultural Code, or by the Secretary of Food and Agriculture or a county agricultural commissioner pursuant to Section 46009 of the Food and Agricultural Code or a federally accredited certification organization.

(c) In order to be registered, a certification organization shall meet all of the following minimum qualifications:

(1) Be the certification organization for at least five legally separate and distinct, financially unrelated, and independently controlled persons involved in the production or processing of food sold as organic.

(2) Be a legally separate and distinct entity from any person whose food is certified by the organization. A certification organization shall be considered legally separate and distinct notwithstanding the fact that persons or representatives of

persons whose food is certified serve as directors, officers, or in other capacities for the certification organization, so long as those persons or representatives of those persons do not exercise decisionmaking authority over certification of that particular food.

(3) Have no financial interest in the sale of the food, except that fees charged by the certification organization to cover the reasonable costs of operating the certification organization do not constitute a financial interest for purposes of this section.

(d) Effective January 1, 1992, a certification organization which certifies processed food sold as organic, except for processed meat, fowl, or dairy products, shall register with the director and shall thereafter annually renew the registration unless no longer engaged in the activities requiring the registration. Registration shall be on a form provided by the director, shall include the filing of a certification plan as specified in Section 110865 and payment of the fee specified in subdivision (f). The director shall make forms available for this purpose on or before December 1, 1993. The registration form shall include a written statement affirming compliance with all requirements for certification organizations specified in Section 110850 to 110870, inclusive, and confirmation that each component of the organization's certification plan has been filed as specified in Section 110865. The director shall reject a registration submission that is incomplete or not in compliance with this article.

(e) Commencing July 31, 1991, the director may, upon the request of a sufficient number of persons to fund the program's cost, establish and maintain a certification program for processors of food sold as organic and shall establish and collect a fee from all processors of food certified under that program to cover all of the department's costs of administering the program. The certification program shall be subject to all provisions regarding certification organizations contained in this article, except that the requirements of subdivisions (c) and (d) shall not apply, and the program shall meet all of the requirements for federal certification programs, including federal accreditation.

(f) The registration fee shall be five hundred dollars ($500), unless the certification organization is also registered as a certifier of producers by the Secretary of Food and Agriculture under Section 46009 of the Food and Agricultural Code, in which case the registration fee shall be one hundred dollars ($100).

(g) The director may audit the organization's certification procedures and records at any time. Records of certification organizations not otherwise required to be released upon request or made publicly available shall not be released by the director except to other employees of the department, the Department of Food and Agriculture, a county agricultural commissioner, the Attorney General, any prosecuting attorney, or any government agency responsible for enforcing laws related to the activities of the person subject to this part.

110855. Prior to initial certification of a producer, a registered certification organization shall conduct at least one initial physical inspection of the premises where the food to be certified is produced. This inspection shall include the recordkeeping system necessary for compliance with Section 110840 and the area or facility at which the food is produced.

110860. (a) A registered certification organization shall no less often than, at the end of each calendar quarter, prepare a list by name of all persons whose production or

processing of food is certified or pending certification by the certification organization. This list shall be filed with the department or the Department of Food and Agriculture, as applicable, by the certification organization and made publicly available within 30 days after the end of each quarter.

(b) A registered certification organization or a federally accredited certification organization shall, at least annually, physically inspect the premises where the food to be certified is produced and processed. The inspection shall include an examination of recordkeeping.

110865. A registered certification organization shall adopt and adhere to a certification plan filed annually and made publicly available. Except in the case of a certification program established pursuant to subdivision (e) of 110850, a certification plan shall be filed as part of the registration required pursuant to subdivision (d) of Section 110850. A certification plan shall at minimum include a detailed description of all of the following elements of the certification organization's program:

(a) Minimum information required from producers or processors regarding growing or processing practices and methods for verifying that information.

(b) Qualifications of and training requirements for all inspectors.

(c) Procedures for inspection, including frequency and items covered.

(d) Procedures for soil and tissue sampling and analysis.

(e) Criteria for certification.

(f) Process for certification decisionmaking, including identification of persons with decisionmaking authority.

110870. (a) Only food that has been produced, handled, and processed in accordance with this article may be certified by a registered certification organization.

(b) Processed or multiingredient food sold as organic may only be certified if all the organic ingredients are certified.

110875. (a) Every person engaged in this state in the processing or handling of processed food sold as organic, including the handling or processing of fish or seafood sold as organic, except for processors and handlers of processed meat, fowl, or dairy products, shall register with the director, and shall thereafter annually renew the registration unless no longer so engaged. Processors and handlers of processed food that are registered with the department pursuant to Article 2 (commencing with Section 110460) shall register under this section in conjunction with the annual renewal of their registration pursuant to that article. All others required to register under this subdivision shall register within 30 days of forms being made available for this purpose. Any processor or handler of processed foods required to register under this subdivision that does not pay the registration fee required by subdivision (c) within 30 days of the date on which the fee is due and payable shall pay a penalty of 1 percent per month on the unpaid balance.

(b) Registration shall be on a form provided by the director and shall be valid for a period of one calendar year from the date of validation of the completed registration form. The director shall make forms available for this purpose on or before January 1, 1994. The information provided on the registration form shall include all of the following:

(1) The nature of the registrant's business, including the types and quantities of each type of product that are sold as organic.

(2) The total current annual gross sales in dollars of products sold as organic.

(3) The names of all certification organizations and governmental entities, if any, providing certification to the registrant pursuant to this article.

(c) A registration form shall be accompanied by payment of a nonrefundable registration fee of one hundred dollars ($100), payable to the department.

(d) To the extent feasible, the director shall coordinate the registration and fee collection procedures of this section with similar licensing or registration procedures applicable to registrants.

(e) The director shall reject a registration submission that is incomplete or not in compliance with this article.

(f) The director shall provide a validated copy of the completed registration form to the registrant.

(g) Registration forms shall be made available to the public for inspection and copying at the main office of the department. Copies of registration forms shall also be made available by mail, upon written request and payment of a reasonable fee, as determined by the director. Registration information regarding quantity of products sold and gross sales volume in dollars shall be deleted prior to public inspection and copying and shall not be released to any person except other employees of the department, the Department of Food and Agriculture, a county agricultural commissioner, the Attorney General, any prosecuting attorney, or any government agency responsible for enforcing laws related to the activities of the person subject to this part.

(h) The requirements of this section shall not apply to retailers of food sold as organic.

110880. This article shall apply to all food sold as organic within the state, wherever produced, handled, or processed, and to all food produced, handled, or processed in the state, wherever sold as organic; except that in lieu of registration under this article, the director may recognize a certification program operating outside the state that certifies processed food sold as organic, except for processed meat, fowl, or dairy products, as functionally equivalent to a certification organization registered under 110850, so long as that program meets minimum standards substantially similar to those contained in subdivision (c) of Section 110850 and Sections 110855 to 110870, inclusive. The director may administratively establish a procedure whereby certification organizations operating outside the state may apply for and receive recognition.

110885. This article shall not apply to the term "natural" when used in the labeling or advertising of a food.

110890. (a) It is unlawful for any person to sell, offer for sale, advertise, or label any food in violation of this article.

(b) Notwithstanding subdivision (a), a person engaged in business as a distributor or retailer of food who in good faith sells, offers for sale, labels, or advertises any food in reliance on the representations of a producer, processor, or other distributor that the food may be sold as organic, shall not be found to violate this article unless the

distributor either: (1) knew or should have known that the food could not be sold as organic; (2) was engaged in producing or processing the food; or (3) prescribed or specified the manner in which the food was produced or processed.

110895. (a) It is unlawful for any person to certify food in violation of this article.

(b) It is unlawful for any person to certify food as organic unless duly registered as a certification organization pursuant to Section 110850.

(c) It is unlawful for any person to willfully make a false statement or representation, or knowingly fail to disclose a fact required to be disclosed, in registration for a certification organization pursuant to Section 110850.

110900. (a) It is unlawful for any person to produce, handle, or process food sold as organic unless duly registered pursuant to Section 110875.

(b) It is unlawful for any person to willfully make a false statement or representation, or knowingly fail to disclose a fact required to be disclosed, in registration pursuant to Section 110875.

110905. It is unlawful for any person to forge, falsify, fail to retain, fail to obtain, or fail to disclose records pursuant to Sections 110840 and 110845.

110910. It is unlawful for any person to advertise, label, or otherwise represent that any fertilizer or pesticide chemical may be used in connection with the production, processing, or distribution of food sold as organic if that fertilizer or pesticide chemical contains a prohibited material.

110915. (a) In lieu of prosecution, the director may levy a civil penalty against any person who violates this article or any regulation adopted pursuant to this article in an amount not more than five thousand dollars ($5,000) for each violation. The amount of the penalty assessed for each violation shall be based upon the nature of the violation, the seriousness of the effect of the violation upon effectuation of the purposes and provisions of this article, and the impact of the penalty on the violator, including the deterrent effect on future violations.

(b) Notwithstanding the penalties prescribed in subdivision (a), if the director finds that a violation was not intentional, the director may levy a civil penalty of not more than two thousand five hundred dollars ($2,500) for each violation.

(c) For a first offense, in lieu of a civil penalty as prescribed in subdivisions (a) and (b), the director may issue a notice of violation, if he or she finds that the violation is minor.

(d) A person against whom a civil penalty is levied shall be afforded an opportunity for a hearing before the director, upon request made within 30 days after the date of issuance of the notice of penalty. At the hearing, the person shall be given the right to review the director's evidence of the violation and the right to present evidence on his or her own behalf. If no hearing is requested, the civil penalty shall constitute a final and nonreviewable order.

(e) If a hearing is held, review of the decision of the director may be sought by any person within 30 days of the date of the final order of the director pursuant to Section 1094.5 of the Code of Civil Procedure.

(f) A civil penalty levied by the director pursuant to this section may be recovered in a civil action brought in the name of the state.

110920. No fee established and collected pursuant to this article shall exceed the department's costs of regulating and enforcing the provisions of this article related to the function for which the fee is established.

110925. Any fees and civil penalties collected pursuant to this article shall be deposited in the General Fund and, upon appropriation by the Legislature, shall be expended to fulfill the responsibilities of the director as specified in this article.

110930. The director shall, to the extent funds are available, enforce this article applicable to all processors and handlers of processed food sold as organic, including handlers and processors of fish and seafood sold as organic, except for processors and handlers of processed meat, fowl, and dairy products.

110935. The director shall maintain in a central location, and make publicly available for inspection and copying, upon request, a list of all penalties levied within the past five years, including the amount of each penalty, the party against whom the penalty was levied, and the nature of the violation. The list also shall be available by mail, upon written request and payment of a reasonable fee, as determined by the director.

110940. (a) Any person may file a complaint with the director concerning suspected noncompliance with this article by a person over whom the director has responsibility as provided in this article.

(b) The director shall, to the extent funds are available, establish a procedure for handling complaints, including, provision of a written complaint form, and procedures for commencing an investigation within three working days of receiving a written complaint regarding fresh food, and within seven working days for other food, and completing an investigation and reporting findings and enforcement action taken, if any, to the complainant within 90 days thereafter.

(c) The director may establish minimum information requirements to determine the verifiability of a complaint and may provide for rejection of a complaint that does not meet the requirements. The director shall provide written notice of the reasons for rejection to the person filing the complaint.

(d) The responsibilities of the director under this section shall be carried out to the extent funds are available.

110945. This article shall apply notwithstanding any other provision of law that is inconsistent with this article. Nothing in this article is intended to repeal any other provision of law not inconsistent with this article.

110950. The director may adopt any regulations as are reasonably necessary to assist in the implementation of, or to make more specific, the provisions of, this article.

110955. Any reference in law to former Section 26569.11, whether existing or hereinafter enacted, shall be interpreted to refer to this article and Chapter 10 (commencing with Section 46000) of Division 17 of the Food and Agricultural Code as the successor section.

110958. Annually, the director shall compile and publish and submit to the Organic Food Advisory Board a summary of information collected under Section 110875, including, but not limited to, the following:

(a) The total number of registrations received under this section.

(b) The total number and quantity of each type of product sold as organic by all registrants combined.

(c) The total annual organic gross sales volume of all registrants combined, and the median gross annual organic sales of all registrants.

(d) The names of all registrants.

(e) The number of registrants in each of the following ranges of annual gross sales volume:

(1) $0-$5,000
(2) $5,001-$10,000
(3) $10,001-$25,000
(4) $25,001-$50,000
(5) $50,001-$75,000
(6) $75,001-$100,000
(7) $100,001-$125,000
(8) $125,001-$150,000
(9) $150,001-$175,000
(10) $175,001-$200,000
(11) $200,001-$250,000
(12) $250,001-$300,000
(13) $300,001-$400,000
(14) $400,001-$500,000
(15) $500,001-$750,000
(16) $750,001-$1,000,000
(17) $1,000,001-$1,500,000
(18) $1,500,001-$2,000,000
(19) $2,000,001-$2,500,000
(20) $2,500,001-$5,000,000
(21) $5,000,001-$7,500,000
(22) $7,500,001-$10,000,000
(23) $10,000,001-$15,000,000
(24) $15,000,001-$20,000,000
(25) $20,000,001 and above.

(f) The report published pursuant to this section shall present the required information in an aggregate form that preserves the confidentiality of the proprietary information of individual registrants.

ARTICLE 8. Potentially Hazardous Food

110960. It is unlawful for any person to hold or display any potentially hazardous refrigerated food at any temperature above 45 degrees Fahrenheit.

ARTICLE 9. Frozen Foods

110965. (a) No retail food production and marketing establishment shall advertise, label, or otherwise hold out as fresh any meat or fish that has been previously frozen.

(b) For purposes of this section:

(1) "Frozen" means any meat or fish stored in a room or compartment in which the temperature is plus five degrees Fahrenheit or lower.

(2) "Retail food production and marketing establishment" means any room, building, or place, or portion thereof, maintained, used, or operated for, or in conjunction with, the retail sale of food, or preparation of food. "Retail food production and marketing establishment" does not include any food facility, such as any "mobile food preparation unit" any "vehicle," and any "vending machine" as defined in Chapter 4 (commencing with Section 113700) of Part 7; any wholesale food manufacturing, distributing, or storage establishment, including, but not limited to, the licensed premises or branch office of any winegrower, any brandy manufacturer, or any wine blender, subject to Chapter 4 (commencing with Section 111950) of Part 6; any frozen food locker plant subject to Chapter 7 (commencing with Section 112500) of Part 6; any health facility subject to Chapter 2 (commencing with Section 1250) of Division 2 and Section 127050; any community care facility subject to Chapter 3 (commencing with Section 1500) of Division 2; or any "official establishment" subject to Chapter 4 (commencing with Section 18650) of Part 3 of Division 9 of the Food and Agricultural Code.

(c) On and after the effective date of the act that added this subdivision to this section during the 1993-94 Regular Session, Section 26661 of the Food and Agricultural Code shall apply, to the exclusion of any provision of this section, with respect to the advertising, labeling, or otherwise holding out, of poultry.

110975. The following definitions apply to this article:

(a) "Ice" means the product obtained as the result of freezing water by natural, mechanical, or artificial means.

(b) "Natural ice" means the product obtained as the result of freezing water by natural means.

110980. In addition to the requirements of this article, unless ice is otherwise specifically excluded, regulations specifying good manufacturing practices applicable to

food generally pursuant to Section 110105 shall be applicable to the manufacture of ice.

110985. No person shall make ice from, or cut natural ice from, water that does not comply with primary drinking water standards adopted by the department pursuant to Section 116365. No person shall sell or offer for sale for human consumption or food preservation ice made or cut in violation of this article.

110990. Unless water from a public water system, as defined in Section 116275, is used in the manufacture of ice, the manufacturer shall, on a quarterly basis, obtain from an approved laboratory, a bacterial analysis of the water used. The analysis shall be submitted to the department, indicating whether the water is pure and wholesome.

110995. Any person or entity who manufactures, transports, stores, or sells ice shall comply with all of the following:

(a) A room in which ice is manufactured shall be used for no other purpose than the manufacture of ice and the production of refrigeration, and may contain refrigeration equipment and machinery. This subdivision shall not apply to any food facility as defined in Section 113785.

(b) Ice storage or processing areas shall be maintained in a clean and sanitary condition and no noxious or offensive odors, smoking, or other air pollution shall be permitted therein.

(c) Cover tops for tank cans shall have a smooth, painted, or treated surface, and shall be cleaned daily. Water used for cleaning shall not be permitted to drip into freezing cans. Only potable water shall be used in sprays and in the thaw tanks for the removal of ice from cans. Water coverage tanks shall be covered and provided with filtered vents.

(d) Crushed, cubed, or shaved ice, intended for human consumption, shall be stored in a manner that prevents its pollution or contamination.

(e) Soil, waste, or drain pipes shall not be installed or maintained above any ice platform, loading space, ice container, ice storage room, dip tank or any place where leakage from the pipes may drop into, or upon any ice or upon any area or equipment used in the manufacture of ice, unless a safety device shall be installed under the pipes drained to an open receptacle or drain so as to prevent pollution of ice, water, or equipment used in the manufacture of the ice.

(f) Block ice-loading platforms shall be washed with water as often as necessary to keep them in a clean and sanitary condition, but not less than once each day.

(g) Block ice pullers and block ice storage-room employees shall wear rubber overshoes while on duty. The rubber overshoes shall be removed when the employee leaves the storage or tank room, except that if the rubber overshoes are not removed, they shall be cleaned and disinfected before reentering the storage or tank room. The use of street shoes without rubber overshoes in these areas is prohibited.

(h) All frozen unpackaged ice blocks intended for sale for human consumption or for the refrigeration of food products shall be washed thoroughly with potable water. Ice manufactured for industrial purposes need not be washed prior to shipping but shall be handled and stored separately from ice intended for human consumption.

(i) Ice shall be handled only with clean tongs, ice-carrying bags, scoops, or other sanitary containers, and shall not be directly handled with bare hands.

(j) Single service supplies shall be stored, dispensed, and handled in a sanitary manner and shall be used only once.

(k) Persons not directly involved in the manufacture, processing, packaging, or storing of ice, in the maintenance of facilities and equipment used therefore, or in the management, supervision, or inspection thereof, shall not be permitted in any area where ice is manufactured, processed, packaged, or stored unless personal cleanliness and hygienic practices are taken to prevent contamination of the product. These areas shall have signs posted to this effect.

(l) Bacteriological tests of the finished ice shall be conducted not less than biannually, chemical and physical tests annually, and radiological tests every four years, to insure that ice manufactured for human consumption or for the refrigeration of food products complies with the primary drinking water standards adopted by the department pursuant to Section 116365.

(m) No ice produced out of state shall be sold or distributed within this state unless it complies with this article.

111000. (a) Filter beds and any filtering equipment shall be designed to protect ice from contamination and shall be subject to periodic treatment and cleaning.

(b) All equipment and utensils used in ice production areas shall be of easily cleanable construction, shall be kept clean and in good repair, and shall be handled and stored in a sanitary manner. Materials used as ice contact surfaces shall be smooth, nontoxic, and nonabsorbent. Ice cans shall be leakproof and the inner surfaces of the containers shall be free of corrosion.

(c) Freezing tank covers shall be designed and constructed to protect ice containers from splash, drip, and other contamination, shall be easily cleanable, and shall be kept clean and in good repair. The covers shall be equipped with rings or similar devices when hooks are used for pulling. Can or tank covers, and the ledges or sides of the tank upon which the cover rests, shall be cleaned as often as necessary to keep them in a sanitary condition.

(d) Conveyor surfaces shall be of impervious material and shall protect ice from contaminants that may result from shredding, flaking, peeling, or fragmentation of the conveyor surface.

(e) Equipment lubrication shall not contaminate the ice and only food grade lubricants shall be used.

(f) All product storage and holding areas to be refrigerated shall be cleaned as often as necessary to keep them free of contamination.

(g) Air used for water agitation shall be filtered or otherwise treated to remove dust, dirt, insects, and extraneous material. Filters shall be placed upstream from the compressor and shall be easily removable for cleaning or replacement.

(h) The compressor or blower used to supply air or water agitation shall be designed to deliver oil-free air.

(i) Air lines and core or vacuum devices shall be used as needed to produce ice free of rust or other foreign materials.

111005. In addition to the requirements of this article, ice shall be considered a food subject to all the sanitation requirements applicable to food generally pursuant to Article 1 (commencing with Section 110425), except those provisions that specifically exclude ice.

111010. Any truck, vehicle, or other equipment used for delivery, distribution, or selling ice, shall comply with all of the following:

(a) It shall be constructed and maintained to provide adequate and reasonable protection to the ice transported therein. Care shall be taken to prevent its contact with any contaminants, or other substances that would take the ice out of compliance with the drinking water standards prescribed by this article.

(b) All cubed, crushed, or shaved ice shall be kept in clean receptacles or containers that shall be kept covered while the vehicle is in motion.

ARTICLE 11. Local Enforcement

111015. "Health officer," as used in this article, means the health officer appointed by a county board of supervisors pursuant to Section 101000, by the governing body of a city pursuant to Section 101460, by the governing body of a city and county, or by a local health district board pursuant to former Section 940, that is continued in effect as to any existing district by Section 3 of Chapter 380 of the Statutes of 1959.

111020. The department, upon the request of a health officer, may authorize the local health department of a city, county, city and county, or local health district to enforce this part, and the regulations adopted pursuant to this part that pertain to retail food establishments, as defined by regulation, if the department determines that the local health department has sufficient personnel with adequate training to do so. The enforcement shall be limited to the area under the jurisdiction of the local health department.

111025. The department may revoke any authorization made pursuant to this article, if it determines, after a hearing conducted pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code that the local health department authorized pursuant to this article is not enforcing this part or the regulations adopted pursuant to this part, or no longer has an adequate staff qualified to do so.

111030. A local health department that is authorized by the department to enforce this part may make inspections, take samples, make laboratory examinations, impose and remove embargoes, hold informal hearings, certify facts to the district attorney, and institute proceedings for the forfeiture, condemnation, and destruction of food found to be adulterated or misbranded. The action shall be instituted in the name of the city, county, city and county, or district of which the local health department is a part, and shall conform to the requirements of this part and the regulations adopted by the department pursuant to this part.

111035. For the purposes of this article, the health officer and his or her deputies shall have the same powers and authority as an inspector of the Bureau of Food and Drug of the department.

111040. When an examination or analysis made pursuant to this part shows that any provision of this chapter has been violated, written notice of that fact together with a copy of the findings shall be furnished to each party from whom the sample was obtained, or who issued the product guarantee.

111045. The health officer shall set a time for an informal hearing, at which the parties may be heard before him or her or his or her representatives. A notice in writing shall be served upon the interested parties at least 15 days prior to the hearing. The informal hearing shall be private and limited to questions of fact. Appearances may be made in person or by attorney. Testimony may be taken and evidence introduced as to the correctness of the findings made by the person making the examination or performing the analysis.

111050. If the examination or analysis is found to be correct, or if any party fails to appear after notice has been duly given, the health officer may certify the facts found to the district attorney of the county. No publication shall be made until after the hearing is concluded.

111055. This article shall not be construed as repealing, either directly or by implication, any of the existing sections of this chapter, but shall be construed as constituting an alternative method of enforcing this part.

111060. This article shall not affect any previous authorization by the department to a local health department of a county, city, or city and county to enforce this part.

111065. The department may adopt regulations relating to the operation of a local health department as it considers necessary to fully effect this article, including, but not limited to, requirements relating to reporting of activities and the numbers and qualification of personnel.

ARTICLE 12. Bottled, Vended, Hauled, and Processed Water

111070. (a) "Bottled water," means any water that is placed in a sealed container at a water-bottling plant to be used for drinking, culinary, or other purposes involving a likelihood of the water being ingested by humans. Bottled water shall not include water packaged with the approval of the department for use in a public emergency.

(b) "Vended water" means any water that is dispensed by a water-vending machine, retail water facility, or water from a private water source, or other water as defined in Section 111170 that is not placed by a bottler in sealed containers, and that is dispensed by a water-vending machine, retail water facility, water hauler, or any other person or facility for drinking, culinary, or other purposes involving a likelihood of the water being ingested by humans. "Vended water," does not include water from a public

water system that has not undergone additional treatment. Water sold without further treatment is not "vended water" and shall be labeled in accordance with paragraph (10) of subdivision (a) of Section 111170.

(c) "Water-bottling plant" means any facility in which bottled water is produced.

(d) A "water-vending machine" means any self-service device that, upon insertion of a coin, coins, or token, or upon receipt of payment by any other means, dispenses a unit volume of water to be used for drinking, culinary, or other purposes involving a likelihood of the water being ingested by humans.

(e) "Water hauler," means any person who hauls water in bulk by any means of transportation if the water is to be used for drinking, culinary, or other purposes involving a likelihood of the water being ingested by humans.

"In bulk," as used in this subdivision, means containers having capacities of 250 gallons or greater.

(f) "Retail water facility" means any commercial establishment where vended water is sold, and placed in customer' s containers, or placed in containers sold or given to customers who come to the establishment to obtain water.

(g) "Private water source," means a privately owned source of water, other than a public water system, that is used for bottled or vended water and meets the requirements of an approved source for bottled water as defined in Section 129.3 of Title 21 of the Code of Federal Regulations.

(h) "Bottled water distributor" means any person, other than an employee or representative of a bottled water plant, who delivers bottled water directly to customers.

111075. (a) Any person who processes, packages, distributes, transfers, or stores bottled water or vended water shall comply with the good manufacturing practices described in Part 129 of Title 21 of the Code of Federal Regulations.

(b) Prior to bottling or vending water, the water shall be subjected to filtration and effective germicidal treatment by ozone, ultraviolet, carbon dioxide, or an equivalent disinfection process approved by the department, except that the requirements for filtration and germicidal treatment shall not apply to mineral water as defined in and from a source that is subject to the council directive of the European Economic Community pertaining to natural mineral waters, dated July 15, 1980, or that is subject to any other natural mineral water standard in the country of origin that prohibits filtration and germicidal treatment, so long as both of the following conditions are met:

(1) The source and product are certified by the responsible authority in the country of origin as complying with microbiological standards at least equal to the standards of this article.

(2) The product complies with microbiological standards of this article.

(c) Bottled or vended water that originates from a surface water source that is not protected from surface contamination shall be subjected to ozonation, filtration, or another effective process that removes or destroys the cysts of the parasite Giardia lamblia. For the purposes of this section, a spring house, catchment basin, storage tank, or bore hole adjacent to a natural spring water source as defined in paragraphs (3) and (8) of subdivision (e) of Section 111170, is not a surface water source.

(d) Ollas or other water-holding dispensers, both refrigerated and nonrefrigerated, water-vending machines, and water dispensers in retail water facilities,

shall be examined for cleanliness each time they are serviced by the distributor, bottler, retail water facility, or water-vending machine operator. When necessary, these dispensers shall be sanitized according to the methods described in Part 129 of Title 21 of the Code of Federal Regulations.

(e) Sanitary operations, equipment procedures, and process controls used in the treatment, storage, transport, or dispensing of water at a retail water facility shall comply with the good manufacturing practices described in the following provisions of Part 129 of Title 21 of the Code of Federal Regulations: subdivisions (a) to (c), inclusive, of Section 129.37; Section 129.40; and subdivisions (a), (c), (d), and (h) of Section 129.80.

(f) Sanitary operations, equipment, procedures, and process controls used in the treatment, storage, transfer, transport, or dispensing of water by water haulers, shall comply with the good manufacturing practices described in the following provisions of Part 129 of Title 21 of the Code of Federal Regulations: subdivisions (a) and (b) of Section 129.37; Section 129.40; and subdivisions (a), (c), (d), and (h) of Section 129.89.

(g) The design and construction of wells, bore holes, catchment basins, spring houses, storage tanks, or other water-contact equipment used by private water sources shall comply with the requirements of the local regulatory authority. Sanitary operations, equipment procedures, and transfer controls used in the treatment, storage, transfer, or dispensing of water by private water source operators shall comply with the good manufacturing practices described in the following provisions of Part 129 of Title 21 of the Code of Federal Regulations: subdivision (a) of Section 129.37; Section 129.40; and subdivisions (a), (c), (d), (g), and (h) of Section 129.80.

(h) Bottled water may be processed through lines used also for other food products under the following conditions:

(1) Process lines, including storage tanks and associated equipment, shall be used exclusively for the production of bottled water, except for filling equipment, that may be used also for filling other food products.

(2) Before being used for the bottling of water, filling equipment that is designed to be cleaned in-place and that is used for filling other food products shall be thoroughly cleansed and sanitized in-place in accordance with the manufacturer's specifications and in compliance with Section 129.80 of Title 21 of the Code of Federal Regulations and the supplementary procedures that follow in paragraphs (3) to (7), inclusive, of this section.

(3) Immediately following completion of filling operations for any other food product other than water, the filler shall be thoroughly rinsed internally and externally with potable water.

(4) In accordance with filler manufacturer's instructions, any parts that are not designed to be cleaned in-place shall be disassembled and removed. All of these parts shall be cleansed and sanitized prior to reassembly using appropriate cleansing and sanitizing procedures, as specified in subdivisions (c) and (d) of Section 129.80 of Title 21 of the Code of Federal Regulations.

(5) All surfaces of the filler that do not contact food products shall be cleaned manually so as to render all surfaces clean and free of any residues.

(6) The filler shall be prepared and all appropriate connections made in accordance with the filler manufacturer's instructions to place the filler in the clean-in-place mode. The following procedures shall be followed:

(A) An alkaline cleaning solution of appropriate strength shall be recirculated through the filler to provide effective cleaning of all product contact surfaces, with a minimum recirculation time of 20 minutes at a temperature between 140 and 170 degrees Fahrenheit.

(B) The cleaning solution shall be drained and followed with a potable water rinse-to-drain for the removal of all residual cleaner alkalinity. This step may be supplemented by the application of an acidified rinse prior to the potable water rinse in order to neutralize any residual alkalinity on product contact surfaces.

(7) Following reassembly of all parts to place the filler into the product mode and just prior to bottling water, the filler shall be sanitized in-place in accordance with procedures specified in subdivision (d) of Section 129.80 of Title 21 of the Code of Federal Regulations.

(8) Any alternate cleaning, rinsing, or sanitizing operations or processes not described in this section shall be approved in writing by the department.

(i) Bottled water and bulk waters sold at retail shall not contact equipment, lines, tanks, or vehicles used for processing, packaging, holding, or hauling of any nonfood product.

111080. The quality standard requirements for bottled water and vended water, including mineral water, shall include all standards prescribed by Section 103.35 of Subpart B of Part 103 of Title 21 of the Code of Federal Regulations, except that water labeled as mineral water shall exceed 500 milligrams per liter of total dissolved solids and may exceed the quality standards for chloride, copper, manganese, iron, sulfate, and zinc prescribed in Section 103.35 of Title 21 of the Code of Federal Regulations. The department may develop additional standards for chloride, copper, manganese, iron, sulfate, or zinc in mineral water that the department determines are reasonably necessary to protect the public health. In addition, bottled water and vended water, when bottled, shall comply with the following quality standards and any additional quality standards adopted by regulation that the department determines are reasonably necessary to protect the public health:

(a) Bottled water and vended water shall meet all maximum contaminant levels set for public drinking water that the department determines, after public comment, are necessary or appropriate so that bottled water may present no adverse effect on public health. New or revised maximum contaminant levels or monitoring provisions adopted for bottled water by the United States Food and Drug Administration under the federal Food, Drug and Cosmetic Act that are more stringent than the state requirements for bottled water are incorporated into this chapter and are effective on the date established by the federal provisions unless otherwise established by regulations of the department.

(b) Bottled and vended water shall not exceed 10 parts per billion of total triahalomethanes or five parts per billion of lead unless the department establishes a lower level by regulation.

(c) Bottled and vended water shall contain no chemicals in concentrations that the United States Food and Drug Administration or the state department has determined may have an adverse effect on public health.

(d) Mineral water producers that bottle 5,000 gallons, or less, per week shall have until February 1, 1990, to comply with the quality standards for bottled water

pursuant to this paragraph. Mineral water producers may present to the department data on consumption of mineral water and the health effects of inorganic elements that may be present as listed in the bottled water quality standards prescribed by Section 103.35 of Subpart B of Part 103 of Title 21 of the Code of Federal Regulations.

111085. Polycarbonate resins manufactured after January 1, 1988, and intended for use in fabricating containers for water products defined in this article shall not contain in excess of three parts per million residual methylene chloride or in excess of 200 parts per million residual monochlorobenzene unless the department establishes a lower level by regulation. For the purpose of monitoring compliance with this section, the concentration of methylene chloride and monochlorobenzene shall not exceed one part per billion in water. "Polycarbonate resins" means the substances defined by Section 177.1580 of Title 21 of the Code of Federal Regulations except as modified by this section.

111090. Any owner or operator of a water-vending machine or other device from which any operator or customer dispenses vended water shall comply with the following standards of design, construction and sanitation and any additional standards adopted by regulation that the department determines are reasonably necessary to protect the public health. The water-vending machines or devices shall do all of the following:

(a) Comply with the construction and performance standards established by the department or by an independent authority approved by the department.

(b) Be designed and constructed to permit easy cleaning and maintenance of all exterior and interior surfaces.

(c) Have all parts and surfaces that come into contact with the water constructed of approved, corrosive-resistant and nonabsorbent material capable of withstanding repeated cleaning and sanitizing treatment.

(d) Have a recessed or guarded corrosion-resistant dispensing spout.

(e) Be designed so that all treatment of the vended water by distillation, ion exchange, filtration, ultraviolet light, reverse osmosis, mineral addition, or any other acceptable process is done in an effective manner.

(f) Have an effective system of handling drip, spillage, and overflow of water.

(g) Have a backflow prevention device approved by the department for all connections with the water supply.

(h) Dispense water disinfected by ultraviolet light or other method approved by the department prior to delivery into the customer's container.

(i) Be equipped with monitoring devices designed to shutdown operation of the machine when the disinfection unit fails to function, or shall be monitored daily at startup and manually shutdown whenever the unit fails to function.

(j) Be equipped with a self-closing, tight-fitting door on the vending compartment, or enclosing the vending spout to protect the vending spout when the water-vending machine is not in use. As an alternative, water-vending machines or other water-dispensing devices may be enclosed in a room with tight-fitting walls, ceilings, and one of the following: a self-closing door, an effective air screen device, or an alternative effective device approved by the department.

(k) Comply with the American Water Works Association (AWWA) specifications for granular activated carbon if used in the treatment of potable water (AWWA B604-74).

(l) Be maintained in a clean and sanitary condition, free from dirt and vermin.

(m) Use a state approved and regulated public water supply or private water source.

(n) Be located in an area that can be maintained in a clean condition and in a manner that avoids insect and rodent harborage.

(o) Be equipped with monitoring devices designed to shut down the labeled purified water delivery system if treatment of water by the machine does not result in a total dissolved solids content of less than 10 milligrams per liter in the purified water. Alternatively, machines shall be monitored daily at startup and manually shutdown whenever the total dissolved solids content exceeds 10 milligrams per liter in the purified water.

111095. It shall be unlawful to operate a bottled plant water plant, water-vending machine, retail water facility, or private water source in violation of the minimum health standards of this article.

111100. It is unlawful for any person to operate a water vending machine in this state that does not satisfy the minimum standards prescribed by this article for the design, construction, and sanitation of water-vending machines.

111105. The department, upon the request of a local health officer, may authorize the local health officer to implement and enforce those provisions of this article that relate to water-vending machines, retail water facilities, and water haulers under the terms and conditions specified by the department.

111110. No water-vending machine shall be used in this state that does not at least satisfy the minimum standards adopted by the department.

111115. The department shall require that each water-vending machine, retail water treatment plant, water hauler vehicle and facility, and private water source be maintained in a clean and sanitary condition at all times.

111120. (a) No person shall operate a water-bottling plant, a private water source, or be a bottled water distributor in this state except pursuant to a license issued by the department. If a person has a valid water-bottling plant license issued by the department, additional license fees for a private water source operator, a retail water facility, a water hauler, or a bottled water distributor based and operating at the same address, shall not be required.

(b) No person shall own or operate a water-vending machine or a retail water facility or be a water hauler, except pursuant to a license issued by the department or to a permit issued by a local health department.

(c) It shall be unlawful for any person to bottle, collect, treat, hold, distribute, haul, vend, or sell bottled water, vended water, operate a retail water facility, or operate a

private water source without the license as required by this article. Any bottled water or vended water dispensed by a retail water facility or a private water source that is not licensed in compliance with this article is misbranded and may be embargoed pursuant to subdivision (e) of Section 111120.

(d) It shall be unlawful for a water bottler, distributor, vendor, retail water facility operator, or private water source operator to sell or otherwise distribute water that is adulterated, as defined in Section 110445, 110545, 110560, or 110565, or that is misbranded as defined in Article 6 (commencing with Section 110660) of Chapter 5.

(e) For the purposes of enforcing this section, water may be embargoed pursuant to Section 111860 in its immediate container, well, spring, spring vault, holding tank, water hauling vehicle, retail water treatment system, spigot, or pipe if there is reasonable cause to believe that it is adulterated.

(f) Any retail water facility, water vendor, or water hauler that violates this article may be subjected to the same penalty and enforcement procedure provided for violation of this article by a water bottling facility.

111125. No bottled water produced in an out-of-state bottling plant shall be sold or distributed within this state unless either the out-of-state bottler or the distributor shall have first obtained a bottler's or distributor's license.

111130. (a) The department shall charge and collect a fee for each license application submitted in accordance with the fee schedule in Table 1, that shall be an amount reasonably necessary to produce sufficient revenue to enforce this article. The fees collected shall be adjusted annually as required by Section 100425. New applicants for a water bottling plant license shall pay Category 2 fees for the first license year.

(b) The water-bottling plant and bottled water distributor categories shall be determined by dividing by 52 the number of gallons produced or shipped into California during the previous year. If the result is an average of 5,000 gallons or less per week, the firm is Category 1. If the average exceeds 5,000 gallons per week, the firm is Category 2.

Table 1
License Fees

License Class	Annual Fee
Water-Bottling Plant	
Category 1	$310
Category 2	875
Water-Vending Machine	10.25
Water Hauler	310
Retail Water Facility	310
Private Water Source Operator	310
Bottled Water Distributor	310

(c) The owners or operators of each water-bottling plant, retail water facility, private water source, each water hauler in California and bottlers or distributors of water bottled out-of-state shall make application for a license on forms provided by the department. Applications and license fees shall be submitted for each calendar year.

(d) Each water-vending machine owner or operator shall make application each calendar year for a license for all machines on forms provided by the department. A decal or seal provided by the department indicating a license fee has been paid shall be affixed in a prominent place to each water-vending machine in service.

111135. The department may deny any license application or revoke or suspend any license issued for cause. The department shall inform the person of any denial, revocation, or suspension in writing, stating with particularity reasons for the denial, revocation, or suspension.
"Cause," as used in this section, means a violation of any provision of this chapter or any regulation adopted pursuant thereto.

111140. The department shall charge and collect a fee for each department evaluation required to issue a new license for a water-vending machine model or a retail water facility to determine compliance with standards established by this article. The fee shall be three hundred dollars ($300) and shall be adjusted annually as required by Section 100425.

111145. (a) The department shall require each bottler, distributor, or vendor of bottled water, each owner or operator of any water-vending machine, each water hauler, each retail water facility operator, each private water source operator, and each applicant for a license, to test for all substances necessary to establish conformance to standards adopted pursuant to Section 111080 at the times and frequencies the department may reasonably establish.

(b) Each product dispensed by a water-vending machine or a retail water facility shall be sampled and analyzed for coliform bacteria at least once every six months. The analysis shall be submitted to the department indicating whether the water is pure and wholesome. Analysis of vended water or water from retail water facilities shall be submitted to the local health officers if the local health officers are authorized by the department pursuant to subdivision (b) of Section 111105.

(c) Purified waters from retail water facilities shall be analyzed by the operator for dissolved solids by conductivity measurement not less frequently than once every seven days.

(d) Purified water from vending machines shall be analyzed by the operator for the dissolved solids by conductivity measurement each time the vending machine is serviced.

111150. (a) All sources of bottled water, vended water, and water dispensed by a retail water facility shall be monitored annually for the presence of volatile organic compounds of potential public health concern, as specified by the United States Environmental Protection Agency in Tables 2 and 14 contained in Volume 50 of the Federal Register on pages 46904, 46923, and 46924 on November 13, 1985, or as reasonably specified by the department as a condition of licensure.

(b) In lieu of source water monitoring required by this section, a water bottler, water vendor, or a retail water facility may document that the source monitoring required by this section is conducted by another entity approved by the department, or may comply with the treatment requirements of subdivision (c).

(c) Detection in the source water of a volatile organic compound, except trihalomethanes, for which source monitoring is required pursuant to this section shall be followed immediately by a program of periodic monitoring by the water bottler, water vendor, or retail water facility to confirm the presence or absence in the source water of the volatile organic compound. If the volatile organic compound is confirmed to be present in the source water it shall be treated using granular activated carbon treatment or an equivalent treatment operated in accordance with good manufacturing practices as provided in Section 129.80 of Title 21 of the Code of Federal Regulations until the time that the concentration of the volatile organic compound does not exceed either one part per billion, or any United States Environmental Protection Agency or United States Food and Drug Administration level for drinking water, or a maximum contaminant level established by the department for bottled water.

(d) The department may exempt any water bottler, water vendor, or retail water facility from the monitoring requirements of this section for any source based on a showing satisfactory to the department that the source (1) does not contain the volatile organic compound for which monitoring is required and (2) is not vulnerable to contamination by the volatile organic compound because for surface water sources the compounds are not applied, manufactured, stored, disposed or shipped upstream, and for groundwater sources, the compounds are not applied, manufactured, stored, disposed, or shipped in the groundwater recharge basin.

111155. Notwithstanding any other provisions of this article, the department may require any bottler, distributor, or vendor of bottled water, any owner or operator of a water-vending machine, any water hauler, any retail water facility operator, any private water source operator, or any applicant for a license to test and submit results to the department for any substance, including organic chemical contaminants, at any time that the department believes the substance may be present in the water source and threaten the public health.

111160. (a) Upon a determination by the department that a particular water source is subject to potential contamination, the department shall notify the bottler, distributor, or vendor of bottled water, the owner and operator of any water-vending machine, any water hauler, any retail water facility operator, or any private water source operator of the specific contaminants or class of contaminants that pose a potential health risk.

(b) Within 90 days after notification by the department, the bottler, distributor, vendor of bottled water, the owner and operator of any water-vending machine, any water hauler, any retail water facility operator, or any private water source operator shall conduct an analysis of the water source and submit the results of the analysis to the department.

(c) If evidence of contamination is found, the department may, by order, require the bottler, distributor, vendor of bottled water, or the owner and operator of any water-vending machine, any water hauler, any retail water facility operator, or any private water source operator to conduct a source and product water analysis for the contaminants of concern in accordance with conditions specified by the department. The water analysis shall be conducted and reported on an annual basis, unless the department finds that reasonable action requires either more frequent or less frequent analysis.

(d) The department may, by order, require the bottler, distributor, vendor of bottled water, the owner and operator of any water-vending machine, any water hauler, any retail water facility operator, or any private water source operator to reduce or eliminate the concentration of any chemical that the department determines may have an adverse effect on public health. Until an enforceable standard has been established for a chemical that may have an adverse effect on human health, the department may require treatment techniques to reduce the concentration of the contaminants that require treatment, in the department's judgment, to prevent known or anticipated adverse effects on the health of persons. The treatment system shall be designed to meet criteria designated by the department or by an independent authority approved by the department.

(e) The department may grant variances from the requirements of subdivision (d), if the bottler, distributor, vendor of bottled water, the owner and operator of any water-vending machine, any water hauler, any retail water facility operator, or any private water source operator demonstrates either of the following:

(1) That the prescribed treatment technique is not necessary to protect the health of consumers because its water source is not subject to, nor is it likely to be subject to, significant chemical contamination.

(2) An alternative treatment technique is at least as efficient in lowering the level of contaminants to be controlled.

111165. All testing of bottled water, bottled water sources, water distributed by water haulers, water from retail water facility, and water from vending machines shall be done by laboratories approved by the department, laboratories certified by the United States Environmental Protection Agency, laboratories certified by the primary enforcement authority in states that have been granted primacy by the United States Environmental Protection Agency, or laboratories certified (accredited) by a third-party organization acceptable to a primacy state.

111170. (a) Labeling and advertising of bottled water and vended water shall conform with this section and Chapter 4 (commencing with Section 110290) and Part 101 of Title 21 of the Code of Federal Regulations.

(b) Each container of bottled water sold in this state, each water-vending machine, and each container provided by retail water facilities located in this state shall be clearly labeled in an easily readable format. Retail water facilities that do not provide labeled containers shall post, in a location readily visible to consumers, a sign conveying required label information.

(c) Water-vending machines, retail water facilities, and private water sources that sell water at retail shall display in a position clearly visible to customers the following information:

(1) The name and address of the operator.

(2) The fact that the water is obtained from an approved public water supply or licensed private water source.

(3) A statement describing the treatment process used.

(4) If no treatment process is utilized a statement to that effect.

(5) A telephone number that may be called for further information, service, or complaints.

(d) Bottled water may be labeled "drinking water," notwithstanding the source or characteristics of the water, only if it is processed pursuant to the Food and Drug Administration Good Manufacturing Practices contained in Section 103.35 and Parts 110 and 129 of Title 21 of the Code of Federal Regulations, Sections 12235 to 12285, inclusive, of Title 17 of the California Code of Regulations, and any other requirements established by the department pursuant to Sections 111145, 111150, and 111155. Any vended water and any water from a retail water facility may be labeled "drinking water," notwithstanding the source or characteristics of the water, only if it is processed pursuant to Article 10 (commencing with Section 114200) of Chapter 4 of Part 7 and any other requirements established by the department pursuant to Sections 111145, 111150, and 111155.

111175. (a) In addition to the requirements of Section 111170, if a bottler, distributor, water hauler, retail water facility operator, or vending machine operator provides information in the labeling or advertising stating or implying that this water is of a specific water type (for example, "spring water") or treated in a specific manner (for example, "purified"), the type or treatment shall be clearly labeled in an easily readable format. In order to be so labeled, the source or treatment shall conform to the following criteria:

(1) "Artesian well water" means water from a well tapping an aquifer in which the water level will stand above the bottom of the confining bed of the aquifer, and in which the hydraulic pressure of the water in the aquifer is greater than the force of gravity. Artesian well water shall not be altered by the addition or deletion of minerals or by blending it with water from a nonartesian well water source, except that artesian well water may be filtered and shall be treated with ozone or an equivalent disinfection process.

(2) "Fluoridated water" means water containing naturally occurring or added fluoride. The label shall specify whether fluoride is naturally occurring or is added. Any water that meets the designation of this paragraph shall contain not less than 1.0 milligrams per liter fluoridization and otherwise comply with the Food and Drug Administration quality standards set forth in Section 103.35(d)(2) of Title 21 of the Code of Federal Regulations.

(3) "Mineral water" means bottled water or vended water containing more than 500 milligrams per liter of total dissolved solids and originating entirely from an underground source, that may be a well, artesian well, or spring. Bottled or vended mineral water may be derived from a natural orifice or from a bore hole adjacent to the natural orifice. If it is derived from a natural orifice or from a bore hole adjacent to the natural orifice, the water shall be from the same underground stratum and be of the same quality and composition as the water derived from the natural orifice without external force. Mineral water may not be altered by the addition or deletion of minerals or by blending it with water from a nonmineral water source, except that mineral water may be filtered and shall be treated with ozone or an equivalent disinfection process approved by the department and shall be treated to reduce the concentrations of any naturally occurring substance that exceeds the bottled water safety standards established by the department. Mineral water may be collected and transported by pipes, tunnels, trucks, or similar devices. Any water that meets the criteria of this paragraph may also be labeled "natural mineral water."

(A) Mineral water that contains carbon dioxide as it emerges from the source and is bottled directly with its entrapped gas, or from which the gas is mechanically separated and later reintroduced into the water at the time of bottling shall be labeled "naturally carbonated" or "naturally sparkling."

(B) Mineral water that contains carbon dioxide, other than that naturally occurring in the source product, shall be labeled with the words "carbonation added" or "carbon dioxide added" when the carbonation is obtained from a natural or manufactured source.

(4) "Mineralized water" means bottled or vended water that meets the requirements of "mineral water" except that the water contains added minerals.

(5) "Natural water" means bottled or vended spring, artesian well, or well water that is unmodified by mineral addition or deletion, except "natural water" may be filtered and shall be sanitized with ozone or an equivalent disinfection process and treated to reduce the concentration of any substance that exceeds safety standards established by the department.

(6) "Naturally sparkling water" means bottled water or vended water with a carbon dioxide content from the same source as the water. "Sparkling," "carbonated," or "carbonation added" means bottled water or vended water that contains carbon dioxide.

(7) "Purified water" means water produced by distillation, deionization, reverse osmosis, or other method meeting the definition of purified water in the 21st edition of the United States Pharmacopeia. Water that meets the designation of this paragraph, and is vaporized, then condensed, may be labeled "distilled water."

(8) "Spring water" means water that issues by natural forces out of the earth at a particular place. Bottled or vended spring water may be derived from the natural orifice

or from a bore hole adjacent to the natural orifice. If it is derived from the natural orifice by external force or from a bore hole adjacent to the natural orifice, the water shall be from the same underground stratum and be of the same quality and composition as the water derived from the natural orifice without external force. Spring water may not be altered by the addition or deletion of minerals or by blending it with water from a nonspring water source, except that spring water may be filtered and shall be treated with ozone or an equivalent disinfection process. Spring water may be collected and transported by pipes, tunnels, trucks, or similar devices.

(9) "Well water" means water from a hole bored into the ground that taps the water of an aquifer, except that well water may be filtered and shall be treated with ozone or an equivalent disinfection process. Well water may not be altered by the addition or deletion of minerals or by blending it with water from a nonwell water source.

(10) Notwithstanding any other provision of this section, water from a public water system that is unprocessed by the bottler or vendor shall be labeled as "unprocessed public drinking water."

111180. Except as provided in Section 111080, any bottled water or vended water, the quality of which is below the quality required by this article, shall be labeled with a statement of substandard quality, as prescribed by Section 103.35 of Title 21 of the Code of Federal Regulations.

111185. Any bottler, distributor, vendor of bottled water, or owner or operator of any water-vending machine or retail water facility, whose corporate name or trademark contains the words "spring" or "springs," or any derivative of either of these words, or "well," "artesian well," or "natural" shall label each bottle or vending machine with the source of the water in typeface at least equal to the size of the typeface of the corporate name or trademark, if the source of the bottled or vended water is different from the source stated in the corporate name or trademark. Retail water facilities that do not provide labeled containers shall post, in a location readily visible to consumers, a sign conveying required label information.

111190. (a) A bottled water, as defined in Section 111170, with natural or added carbonation, may be prepared with added flavors, extracts, essences, or fruit juice concentrates derived from a spice or fruit and comprising less than 1 percent by weight of the final product. The final product shall contain no sweeteners, or additives other than the flavors, extracts, essences, or fruit juice concentrates and carbon dioxide and shall be designated on labels and in advertising as follows:

(1) The common or usual name of the characterizing flavor shall accompany the designation of the bottled water product type as defined in subdivision (b) of Section 111170.

(2) The product may be designated as "natural" only if it meets the requirements for the designation as defined in paragraphs (5) and (6) of subdivision (b) of Section 111170, and naturally derived flavors, extracts, or essences are used.

(b) Products labeled pursuant to this section shall comply with all other provisions of this article. Products with one type or one source of bottled water that are labeled

pursuant to this section shall not be blended with water that is not bottled water or that is of another bottled water type.

111195. The department, prior to issuing a license, shall review all labels prepared pursuant to this article, and may require any changes in order to comply with this article.

ARTICLE 13. Hamburger and Imitation Hamburger

111200. As used in this article, the following definitions shall apply:

(a) "Hamburger" means chopped fresh or frozen beef, or a combination of both fresh or frozen beef, with or without the addition of beef fat as such, and with or without the addition of seasoning. Hamburger shall not contain more than 30-percent fat, and shall not contain added water, binders, or extenders. Beef cheek meat (trimmed beef cheeks) may be used in the preparation of hamburger to the extent of 25 percent, and if in excess of natural proportions, its presence shall be declared on the label in the ingredient statement, if any, and otherwise contiguous to the name of the product.

(b) "Imitation hamburger" means chopped fresh or frozen beef, or a combination of both fresh or frozen beef, with or without the addition of beef fat as such, and with or without the addition of seasoning. Imitation hamburger may contain binders and extenders, with or without the addition of partially defatted beef tissue, without added water or with added water only in amounts that the products' characteristics are essentially that of a meat pattie.

(c) "Restaurant" means restaurants, itinerant restaurants, vehicles, vending machines, or institutions including hospitals, schools, asylums, eleemosynaries, and all other places where food is served to the public for consumption on the premises of sale that are not included within the definitions of the terms restaurants, itinerant restaurants, vehicles, and vending machines.

111205. (a) If imitation hamburger is sold or served in restaurant a list of ingredients thereof shall appear on the menu, or, if there is no menu, the information shall be posted as state department shall by regulations require. No list of ingredients, however, shall be required for imitation hamburger that contains not more than 10 percent added protein and water, and that does not contain other binders or extenders.

(b) No restaurant shall use the terms "hamburger," "burger," or any other cognate thereof in any advertisement, or menu to refer to any imitation hamburger. A restaurant selling or serving imitation hamburger may refer to the product as imitation hamburger or by any other term that accurately informs the customer of the nature of the food product that he or she is sold or served.

111210. It is unlawful and constitutes misbranding for any person to advertise, offer for sale, sell, or serve as hamburger or imitation hamburger in any restaurant any product that does not come within the definitions of those terms contained in Section 111200. It is unlawful and constitutes misbranding for any person to violate any provision of this article or any regulation adopted pursuant thereto.

111215. It is the public policy of this state to require restaurants selling hamburger and imitation hamburger to accurately inform the consumer public of the contents of foods.

111220. This article shall be enforced by the same persons and in the same manner as provided in Article 7 (commencing with Section 28690) of Chapter 11 of Division 22.

CHAPTER 6. DRUGS AND DEVICES

ARTICLE 1. General Provisions

111225. As used in this chapter, with respect to a drug or drug ingredient, "established name" means either of the following:

(a) The name designated pursuant to Section 508 of the federal act (21 U.S.C. Sec. 358).

(b) If there is no such name and the drug or ingredient is an article recognized in an official compendium, then the official title in the compendium is the established name.

If neither subdivision (a) or (b) of this section applies, the common or usual name, if any, of the drug or of the ingredient is the established name. When an article is recognized in the United States Pharmacopoeia and in the Homeopathic Pharmacopoeia under different official titles, the official title used in the United States Pharmacopoeia shall apply unless it is labeled and offered for sale as a homeopathic drug. If it is labeled and offered for sale as a homeopathic drug, the official title used in the Homeopathic Pharmacopoeia shall apply.

111230. Any drug represented in its labeling or advertisement as an antiseptic shall be considered to be represented as a germicide, except in the case of a drug that is purported to be or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or other use involving prolonged contact with the body.

111235. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homeopathic Pharmacopoeia of the United States, it shall be subject to the requirements of the United States Pharmacopoeia unless it is labeled and offered for sale as a homeopathic drug. If it is labeled and offered for sale as a homeopathic drug, it shall be subject to the provisions of the Homeopathic Pharmacopoeia of the United States and not to those of the United States Pharmacopoeia.

111240. Any added poisonous or deleterious substance, or color additive, shall be considered unsafe for use with respect to any drug or device unless there is in effect a regulation adopted pursuant to Section 110090 that prescribes its use in or on drugs or devices.

111245. The department may establish performance standards for devices, that shall be designed to provide reasonable assurance of safe and effective performance and, where appropriate, requiring the use and prescribing the form and content of labeling for

the proper installation, maintenance, operation, or use of the device. However, if a performance standard is established for a device pursuant to Section 514 of the federal act (21 U.S.C. Sec. 360d) or Section 521 of the federal act (21 U.S.C. Sec. 360k), it shall be the performance standard of this state for device.

ARTICLE 2. Adulterated Drugs or Devices

111250. Any drug or device is adulterated if it consists, in whole or in part, of any filthy, putrid, or decomposed substance.

111255. Any drug or device is adulterated if it has been produced, prepared, packed, or held under conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.

111260. Any drug or device is adulterated if the methods, facilities, or controls used for its manufacture, processing, packing, or holding do not conform to, or are not operated or administered in conformity with current good manufacturing practice to assure that the drug or device meets the requirements of this part as to safety and has the identity and strength, and meets the quality and purity characteristics that it purports or is represented to possess.

111265. Any drug or device is adulterated if it is packaged and its container is composed, in whole or in part, of any poisonous or deleterious substance that may render the contents injurious to health.

111270. Any drug or device is adulterated if it bears or contains for the purpose of coloring only a color additive that is unsafe within the meaning of Section 111240.

111275. Any drug or device is adulterated if it is a color additive, the intended use of which in or on drugs or devices is for the purpose of coloring only, and it is unsafe within the meaning of Section 111240.

111280. Any drug is adulterated if it purports to be, or is represented as, a drug that is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standards set forth in the compendium. Such determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in the compendium, or in the absence of or inadequacy of the tests or methods of assay, those prescribed under authority of this part. No drug defined in an official compendium shall be deemed to be adulterated under this section because it differs from the standard of strength, quality, or purity set forth in the compendium, if its difference in strength, quality, or purity from the standard is plainly stated on the label.

111285. Any drug or device is adulterated if its strength differs from, or its purity or quality is below, that which it is represented to possess.

111290. Any drug or device is adulterated if any substance has been mixed or packed with it so as to reduce its quality or strength or if any substance has been substituted, wholly or in part, for the drug or device.

111295. It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated.

111300. It is unlawful for any person to adulterate any drug or device.

111305. It is unlawful for any person to receive in commerce any drug or device that is adulterated or to deliver or proffer for delivery any drug or device.

111310. While any regulation described in Section 110090 relating to any color additive is in effect, any drug or device that bears or contains the color additive in accordance with the regulation shall not be considered adulterated.

111315. Any drug or device intended for export shall not be deemed to be adulterated under this part if it satisfies all of the following requirements:

(a) It accords to the specifications of the foreign purchaser.

(b) It is not in conflict with the laws of the importing country.

(c) It is labeled on the outside of the shipping package to show that it is intended for export.

If the article is sold or offered for sale in domestic commerce, this section shall not exempt it from any of the provisions of this part.

111320. Any device is adulterated that fails to meet the applicable performance standard, if any, as provided in Section 111245.

111325. A drug or device is deemed adulterated under the laws of this state if it is subject to regulations issued by the United States Food and Drug Administration as set forth in Parts 200, 211, 314, and 800 of Volume 21 of the Code of Federal Regulations, as amended, relating to tamper-resistant packaging, but is not in compliance therewith.

ARTICLE 3. Misbranded Drugs or Devices

111330. Any drug or device is misbranded if its labeling is false or misleading in any particular.

111335. Any drug or device is misbranded if its labeling or packaging does not conform to the requirements of Chapter 4 (commencing with Section 110290).

111340. Any drug or device is misbranded unless it bears a label containing all of the following information:

(a) The name and place of business of the manufacturer, packer, or distributor.

(b) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count.

Reasonable variations from the requirements of subdivision (b) shall be permitted. Requirements for placement and prominence of the information and exemptions as to small packages shall be established in accordance with regulations adopted pursuant to Section 110380.

111345. Any drug or device is misbranded if any word, statement, or other information required by or under this part to appear on the label or labeling is not prominently placed on the label or labeling with conspicuousness, as compared with other words, statements, designs, or devices in the labeling, and in terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

111350. Any drug is misbranded if it is for use by man and contains any quantity of the narcotic or hypnotic substances alpha-eucaine, barbituric acid, beta-eucaine, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, marijuana, morphine, opium, paraldehyde, peyote, or sulfonmethane; or any chemical derivative of those substances, that derivative, after investigation, has been found to be and designated as habit forming, by regulations adopted by the department, unless its label bears the name and quantity or proportion of the substance or derivative and in juxtaposition therewith the statement, "Warning--may be habit forming."

Regulations designating habit-forming drugs issued pursuant to Section 502(d) of the federal act (21 U.S.C. Sec. 352(d)) are the regulations designating habit-forming drugs in this state. However, the department may, by regulation, designate habit-forming drugs whether or not these habit-forming drugs are in accordance with the regulations adopted under the federal act.

111355. (a) Any drug is misbranded unless its label bears, to the exclusion of any other nonproprietary name except the applicable, systematic chemical name or the chemical formula, all of the following information:

(1) The established name of the drug, if any.

(2) If it is fabricated from two or more ingredients, the established name and quantity of each active ingredient, including the kind and quantity or proportion of any alcohol, and also including, whether active or not, the established name and quantity or proportion of any bromides, ether, chloroform, acetanilide, acetophenetidin, antipyrine, atropine, hyoscine, hyoscyamine, codeine, arsenic, digitalis, digitalis glycosides, mercury, ouabain, strophanthin, strychnine, barbituric acid, or any derivative or preparation of any substances contained therein.

(b) The requirement for stating the quantity of the active ingredients of any drug, including the quantity or proportion of any alcohol, and also including, whether active or not, the quantity or proportion of any bromides, ether, chloroform, acetanilide, acetophenetidin, antipyrine, atropine, hyoscine, hyoscyamine, codeine, arsenic, digitalis, digitalis glycosides, mercury, ouabain, strophanthin, strychnine, barbituric acid, or any derivative or preparation of any substances contained therein, shall apply to all drugs, including prescription drugs and nonprescription drugs. However, the requirement for declaration of quantity shall not apply to nonprescription drugs that are also cosmetics, as defined in Section 201(i) of the federal Food, Drug, and Cosmetic Act (21 U.S.C.

Sec. 321(i)) and that are labeled in compliance with federal labeling requirements concerning declaration of ingredients including active ingredients and also the quantity and proportion of any alcohol, except that the quantity or proportion of the following ingredients, whether active or not, shall be declared: bromides, ether, chloroform, acetanilide, acetophenetidin, antipyrine, atropine, hyoscine, hyoscyamine, codeine, arsenic, digitalis, digitalis glycosides, mercury, ouabain, strophanthin, strychnine, barbituric acid, or any derivative or preparation of any substances contained therein. The department may exempt any nonprescription drug from the requirement of stating the quantity of the active ingredients, other than those specifically named in this subdivision, upon a showing by the applicant through evidence satisfactory to the department that the granting of the exemption will not endanger the public health. For any prescription drug the established name of the drug or ingredient, as the case may be, on the label and on any labeling on which a name for the drug or ingredient is used shall be printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for the drug or ingredient.

The changes made in this section by Chapter 943 of the Statutes of 1978 shall not apply to any drug shipped by a manufacturer or packer to a retailer or wholesaler before January 1, 1980. Any such drugs so shipped shall comply with this section on and after January 1, 1981.

111360. Any drug subject to Section 111470 is misbranded unless the manufacturer, packer, or distributor of the drug includes, in all advertisements and other descriptive matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that drug, a true statement of all of the following:

(a) The established name, printed prominently and in a type at least half as large as that used for any proprietary name of the drug.

(b) The formula showing quantitatively each ingredient of the drug to the extent required for labels under Section 111355.

(c) The name and place of business of the manufacturer that produced the finished dosage form of the drug, as prescribed by regulations issued by the department. This subdivision applies only to advertisements or descriptive matter issued for drugs manufactured in finished dosage form on or after April 1, 1973.

(d) Such other information, in brief summary relating to side effects, contraindications, and effectiveness as shall be required by regulations promulgated by the department.

Regulations relating to side effects, contraindications, and effectiveness issued pursuant to Section 502(n) of the federal act (21 U.S.C. Sec. 352(n)) are the regulations establishing information requirements relating to side effects, contraindications and effectiveness in this state. The department may, by regulation, make other requirements relating to side effects, contraindications, and effectiveness whether or not in accordance with the regulations adopted under the federal act.

111365. Any drug subject to Section 111470 is misbranded unless the established name of the prescription drug or prescription drug ingredient is printed on the label prominently and in type at least half as large as that used for the proprietary name or designation on the label, labeling, or advertising.

The department may, by regulation, establish exemptions from the requirements of this section when compliance with this section is not considered necessary for the protection of health and safety.

111375. Any drug or device is misbranded unless its labeling bears all of the following information:

(a) Adequate directions for use.

(b) Such adequate warnings against use in pathological conditions or by children where its use may be dangerous to health.

(c) Adequate warning against unsafe dosage or methods or duration of administration or application.

Warnings shall be in a manner and form as are necessary for the protection of users.

If the department determines that any requirement of subdivision (a), as applied to any drug or device, is not necessary for the protection of the public health, the department may adopt regulations exempting the drug or device from these requirements.

Any drug or device exempted under Section 502(f) of the federal act (21 U.S.C. Sec. 352(f)) is exempt from the requirement of this section. The department, however, may adopt any regulation including a drug or device within, or excluding a drug or device from the requirements of this section, whether or not the inclusion or exclusion of the drug or device is in accord with the federal act.

111380. Any drug is misbranded if it purports to be a drug that is recognized in an official compendium and it is not packaged and labeled as prescribed in the official compendium. The method of packaging, however, may be modified with the consent of the department.

111385. Any drug or device is misbranded if the department determines that the drug or device is liable to deterioration, unless it is packaged in that form and manner and its label bears a statement of the precautions, as the department, by regulation, may require as necessary for the protection of public health. Such regulations shall not be established for any drug or device recognized in an official compendium, unless the department has informed the appropriate body, charged with the revision of the official compendium, of the need for that packaging or labeling requirements and that body has not prescribed the requirements in a reasonable length of time.

111390. Any drug or device is misbranded if its container is so made, formed, or filled as to be misleading.

111395. Any drug is misbranded in any of the following cases:

(a) It is an imitation of another drug.

(b) It is offered for sale under the name of another drug.

(c) The contents of the original package have been, wholly or partly, removed and replaced with other material in the package.

111400. Any drug or device is misbranded if it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in its labeling.

111405. Any drug is misbranded if it is, or purports to be, or is represented as, a drug composed wholly or partly of insulin, unless both of the following requirements are satisfied:

(a) It is from a batch to which a certificate or release has been issued pursuant to Section 506 (21 U.S.C. Sec. 356) of the federal act.

(b) The certificate or release is in effect with respect to the drug.

111410. Any drug is misbranded if it is, purports to be, or is represented as a drug composed, wholly or partly, of any antibiotic drug, or any derivative thereof, unless both of the following requirements are satisfied:

(a) It is from a batch to which a certificate or release has been issued pursuant to Section 507 of the federal act (21 U.S.C. Sec. 357).

(b) The certificate or release is in effect with respect to that drug. This section shall not, however, apply to any drug or class of drugs exempted by regulations adopted pursuant to Section 507(c) or 507(d) of the federal act (21 U.S.C. Sec. 357 (c) or 357(d)).

111415. Any drug is misbranded if it is a color additive, intended for use in or on drugs for the purpose of coloring only and its packaging and labeling fail to conform to the packaging and labeling requirements adopted pursuant to Section 110090.

111420. A drug or device is misbranded if a trademark, trade name, or other identifying mark, imprint, or device of another person, or any likeness of the trademark, trade name, or other identifying mark, imprint, or device of another person, has been placed on the drug or device, or upon its container.

111425. A drug or device is misbranded if it was manufactured in this state in an establishment not duly licensed as provided in this part.

111430. A drug or device is misbranded if it was manufactured in an establishment not duly registered with the Secretary of Health, Education, and Welfare of the United States.

111435. Any drug is misbranded if its packaging or labeling is in violation of an applicable regulation issued pursuant to Section 108685 or 108700.

111440. It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded.

111445. It is unlawful for any person to misbrand any drug or device.

111450. It is unlawful for any person to receive in commerce any drug or device that is misbranded or to deliver or proffer for delivery any drug or device.

111455. It is unlawful for any person to alter, mutilate, destroy, obliterate, or remove the label or any part of the labeling of any drug or device if the act results in the drug or device being misbranded.

111460. Any drug or device intended for export shall not be deemed to be misbranded under this part if it satisfies all of the following requirements:

(a) It accords to the specifications of the foreign purchaser.

(b) It is not in conflict with the laws of the importing country.

(c) It is labeled on the outside of the shipping package to show that it is intended for export.

If the article is sold or offered for sale in domestic commerce, this section shall not exempt it from any of the provisions of this part.

111465. A drug or device is deemed misbranded under the laws of this state if it is subject to regulations issued by the United States Food and Drug Administration relating to tamper-resistant packaging, as set forth in Parts 200, 211, 314, and 800 of Volume 21 of the Code of Federal Regulations, as amended, but is not in compliance therewith.

111470. The following drugs or devices, that are intended for use by man, shall be sold only upon a written prescription of a practitioner licensed by law to prescribe the drug or device, or upon an oral prescription of the licensee that is reduced promptly to writing and filed by the pharmacist, or by refilling the written or oral prescription if the refilling is authorized by the prescriber either in the original prescription or by oral order that is reduced promptly to writing and filed by the pharmacist:

(a) A habit forming drug to which Section 111350 applies.

(b) A drug or device that, because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer the drug or device.

(c) A drug or device for which adequate directions cannot be written for persons, who are not practitioners licensed by law to prescribe the drug or device, for safe and effective self-medication or treatment by those persons, who are not practitioners licensed by law to prescribe the drug or device.

(d) A drug or device that is limited by an effective application under Section 505 of the federal act (21 U.S.C. Sec. 355) or Section 111550 to use under the professional supervision of a practitioner licensed by law to administer the drug or device.

If any prescription for the drug does not indicate the number of times it may be refilled, if any, the prescription may not be refilled unless the pharmacist obtains a new order from the practitioner.

111475. The act of selling a drug or device contrary to Section 111470 shall be deemed to be an act that results in the drug or device being misbranded while held for sale.

111480. Any drug or device sold by filling or refilling a written or oral prescription of a practitioner licensed to prescribe the drug or device shall be exempt from the labeling requirements of Sections 111335, 111340, 111350, 111355, 111360, 111365, 111375, 111380, 111385, 111395, 111415, and 111420, if the drug or device bears a label displaying all the following:

(a) Except where the prescriber orders otherwise, either the manufacturer's trade name of the drug, or the generic name and the name of the manufacturer. Commonly used abbreviations may be used. Preparations containing two or more active ingredients may be identified by the manufacturer's trade name or the commonly used name or the principal active ingredients.

(b) The directions for the use of the drug or device.

(c) The name of the patient(s).

(d) The name of the prescriber.

(e) The date of issue.

(f) The name, address of the furnisher, and prescription number or other means of identifying the prescription.

(g) The strength of the drug or drugs dispensed.

(h) The quantity of the drug or drugs dispensed.

(i) The expiration date of the effectiveness of the drug or device if the information is included on the original label of the manufacturer of the drug or device.

If a pharmacist dispenses a prescribed drug by means of a unit dose medication system, as defined by administrative regulation, for a patient in a skilled nursing, intermediate care or other health care facility, the requirements of this section will be satisfied if the unit dose medication system contains the aforementioned information or the information is otherwise readily available at the time of drug administration.

The exemption shall not apply to any drug or device dispensed in the course of the conduct of a business of dispensing drugs or devices pursuant to diagnosis by mail, or to a drug or device dispensed in violation of Section 111470.

111485. The department may, by regulation, remove any drug or device subject to Sections 111350 and 111550 from the requirements of Section 111470, when the requirements are not necessary for the protection of the public health. Any drug removed from the prescription requirements of the federal act by regulations adopted pursuant to the federal act is removed from the requirements of Section 111470. The department may, however, by regulation, continue the applicability of Section 111470 for any drug or device, or make these sections inapplicable to any drug or device, whether or not the inclusion or exclusion of the drug or device is in accordance with the regulations adopted pursuant to the federal act.

111490. A drug or device that is subject to Section 111470 is misbranded if at any time prior to dispensing, its label fails to bear the statement "Caution: federal law prohibits dispensing without prescription," or "Caution: state law prohibits dispensing without

prescription," or "Caution: federal law restricts this device to sale by or on the order of a _____," the blank to be filled in with the designation of the practitioner licensed to use or order use of the device. A drug or device to which Section 111470 does not apply is misbranded if at any time prior to dispensing its label bears the caution statement quoted in the preceding sentence.

111495. Nothing in this article shall be construed to relieve any person from any requirement prescribed by or under authority of law with respect to drugs now included or that may hereafter be included within the classification stated in Division 10 (commencing with Section 11000) or in the applicable federal law relating to controlled substances.

111500. A physician, dentist, podiatrist, or veterinarian may personally furnish his or her own patient with drugs as are necessary in the treatment of the condition for which he or she attends the patient provided that the drug is properly labeled to show all the information required in Section 111480 except the prescription number.

111505. For purposes of Section 111510, the following definitions shall apply:

(a) "Distributor" means any corporation, person, or other entity, not engaged in the manufacture of a legend drug product, who distributes for resale and distribution a legend drug product under the label of the corporation, person, or entity.

(b) "Legend drug" means any controlled substance subject to the Federal Controlled Substances Act (Title II, P.L. 91-513) or subject to the Uniform Controlled Substances Act, Division 10 (commencing with Section 11000), and any drug described in Section 4211 of the Business and Professions Code or Section 111470.

(c) "Solid dosage forms" means capsules or tablets intended for oral administration.

(d) "Code imprint" means a series of letters or numbers assigned by the manufacturer or distributor to a specific drug, or marks or monograms unique to the manufacturer, distributor, or both. The National Drug Code may be used as a code imprint.

111510. (a) No legend drug in solid dosage form may be manufactured or distributed for sale in this state unless it is clearly marked or imprinted with a code imprint identifying the drug and the manufacturer or distributor of the drug. Manufacturers or distributors who only repack an already finished dosage form of a legend drug shall not have the responsibility to do the imprint.

(b) On or before July 1, 1982, manufacturers or distributors of legend drugs, depending on whether the manufacturer's or distributor's code imprint will appear on the surface of the solid dosage form, shall provide to the department a list of their legend drugs and the intended code imprints. The department shall provide for the distribution of the information required to be submitted under this subdivision to all poison control centers in the state. Manufacturers, distributors, and the department shall provide to any licensed health care provider, upon request, lists of legend drugs and code imprints provided to the department under this section, but may charge a reasonable fee to

cover copying and postage costs. Updated lists shall be provided to the department annually or as changes or revisions occur.

(c) The department may grant exemptions from the requirements of this section upon application of a manufacturer or distributor indicating size or other characteristics that render the product impractical for the imprinting required by this section.

(d) A legend drug that does not meet the requirements is misbranded.

(e) It is the intent of the Legislature that all legend drugs having solid dosage forms be imprinted regardless of by whom they are distributed.

(f) This section shall apply to all legend drugs sold in California on or after January 1, 1983.

(g) Pharmacists, pharmacies, and licensed wholesalers shall only be liable for knowing and willful violations of this section, except that no liability shall accrue if the pharmacist acts pursuant to Section 4229.5 of the Business and Professions Code.

(h) The provisions of subdivisions (a) to (g), inclusive, shall not apply to any of the following:

(1) Drugs purchased by a pharmacy, pharmacist, or licensed wholesaler prior to January 1, 1983, and held in stock for resale.

(2) Drugs that are the subject of an investigation pursuant to Section 111590 or 111595.

(3) Drugs that are manufactured by or upon the order of a practitioner licensed by law to prescribe or administer drugs and that are to be used solely by the patient for whom prescribed.

ARTICLE 4. Experimental Use of Drugs

111515. As used in this article, "experimental drug" means any of the following:
A drug intended for investigational use under Section 111595.

111520. No person shall prescribe or knowingly administer an experimental drug to another person in violation of this article.

111525. Prior to prescribing or administering an experimental drug, consent to the use of the drug shall be obtained in the method and manner specified in Chapter 1.3 (commencing with Section 24170) of Division 20.

111530. (a) Notwithstanding the provisions of Section 24175, if the subject is a minor, consent shall be provided by a parent or guardian of the subject and shall also be provided by the subject if the subject is seven years of age or older.

(b) Consent given pursuant to this section shall only be for the prescribing or administering of an experimental drug that is related to maintaining or improving the health of the subject or related to obtaining information about a pathological condition of the subject.

111535. Consent given pursuant to Section 111525 may be revoked at any time by either verbal or written communication to the practitioner supervising the administration of the experimental drug.

111540. Prior to administering an experimental drug, the experimental activity as a whole, including the consent procedures required by Section 111525, shall be reviewed and approved by a committee for the protection of human subjects that is acceptable, as determined by the department. A committee for the protection of human subjects that operates under a general or special assurance approved by the federal Department of Health, Education, and Welfare pursuant to Part 46 of Title 45 of the Code of Federal Regulations shall be an acceptable committee for purposes of this section. A copy of the consent procedures approved by a committee for the protection of human subjects shall be filed with the department prior to the commencement of the experiment.

111545. A person having an ownership interest in a skilled nursing facility or intermediate care facility, as those terms are defined in Section 1250, may not prescribe an experimental drug for a patient in the facility.

ARTICLE 5. New Drugs or Devices

111550. No person shall sell, deliver, or give away any new drug or new device unless it satisfies either of the following:

(a) It is a new drug, and a new drug application has been approved for it and that approval has not been withdrawn, terminated, or suspended under Section 505 of the federal act (21 U.S.C. Sec. 355); or it is a new device for which a premarket approval application has been approved, and that approval has not been withdrawn, terminated, or suspended under Section 515 of the federal act (21 U.S.C. Sec. 360e).

(b) The department has approved a new drug or device application for that new drug or new device and that approval has not been withdrawn, terminated, or suspended. Any person who files a new drug or device application with the department shall submit, as part of the application, all of the following information:

(1) Full reports of investigations that have been made to show whether or not the new drug or device is safe for use and whether the new drug or device is effective in use under the conditions prescribed, recommended, or suggested in the labeling or advertising of the new drug or device.

(2) A full list of the articles used as components of the new drug or device.

(3) A full statement of the composition of the new drug or device.

(4) A full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of the new drug or in the case of a new device, a full statement of its composition, properties, and construction and the principles of its operation.

(5) Samples of the new drug or device and of the articles used as components of the drug or device as the department may require.

(6) Specimens of the labeling and advertisements proposed to be used for the new drug or device.

111555. Within 180 days after the filing of an application provided for in Section 111550, or an additional period as shall be agreed upon by the department and the applicant, the department shall do either of the following:

(a) Approve the application, if it finds that none of the grounds for denying approval specified in Section 111550 apply.

(b) Give the applicant written notice for an opportunity for a hearing before the department on the question of whether the application is approvable. If the applicant elects to accept the opportunity for hearing by written request within 30 days after the notice, the hearing shall commence not more than 90 days after the expiration of the 30 days unless the department and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the department' s order thereon shall be issued within 90 days after the date fixed by the department for filing final briefs.

111560. The department shall issue an order refusing to approve an application if, after written notice to the applicant and after giving him or her an opportunity for a hearing, the department makes any of the following findings:

(a) That the reports of investigation, that are required to be submitted to the department pursuant to Section 111550, do not include adequate tests by all methods reasonably applicable to show whether or not the new drug or device is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling and advertisement of the new drug or device.

(b) That the results of the tests submitted pursuant to Section 111550 to show whether or not the new drug or device is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling and advertisement of the new drug or device show that the drug or device is unsafe for use under these conditions or do not show that the new drug or device is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling and advertisement.

(c) That the methods, facilities, and controls used in the manufacture, processing, or packing of the new drug or device are inadequate to preserve its identity, strength, quality, purity, composition, or other characteristics.

(d) That upon the basis of information submitted as part of the application, or upon the basis of any other information before it with respect to the new drug or device, that the department has insufficient information to determine whether the drug or device is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling and advertisement.

(e) That evaluated on the basis of the information submitted as part of the application and any other information before it with respect to the new drug or device, that there is a lack of substantial evidence that the new drug or device will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling or advertisement of the new drug or device.

(f) That based on an evaluation by the department of all material facts, that the proposed labeling or advertising of the new drug or device is false or misleading in any particular.

111565. An order pursuant to Section 111560 refusing approval of a new drug application or a new device application shall be revoked whenever the department finds that the facts justify the action.

111570. In the case of any new drug or device for which an approval of an application filed pursuant to Section 111550 is in effect, the applicant shall establish and maintain records, and make reports to the department, of data relating to clinical experience and other data or information, received or otherwise obtained by the applicant with respect to the new drug or device, as the department may by general regulation, or by order with respect to the application, prescribe. Any regulation or order issued pursuant to this section or pursuant to Section 111595 shall have due regard for the professional ethics of the medical profession and the interest of patients and shall provide, where the department determines that it is reasonably necessary, for the examination upon request, by the persons to whom the regulation or order is applicable, of similar information received or otherwise obtained by the department. Every person required pursuant to this section to maintain records, and every person in charge or in custody of the records, shall, upon request of an authorized agent of the department, permit the agent at all reasonable time to have access to, and copy and verify, the records.

111575. The department shall issue an order withdrawing approval of an application concerning any new drug or device if, after giving written notice to the applicant and an opportunity for a hearing, the department makes any of the following findings:

(a) That clinical or other experience, tests, or other scientific data show that the new drug or device is unsafe for use under the conditions of use upon the basis of which the application was approved.

(b) That new evidence of clinical experience, not contained in the application or not available to the department until after the application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when the application was approved, evaluated together with the evidence available to the department when the application was approved, shows that the new drug or device is not shown to be safe for use under the conditions of use upon the basis of which the application was approved.

(c) On the basis of new information with respect to the new drug or device, evaluated together with the evidence available to the department when the application was approved, that there is a lack of substantial evidence that the new drug or device will have the effect it purports or is represented to have, under the conditions of use prescribed, recommended, or suggested in the labeling or advertising of the new drug or device.

(d) That the application contains any untrue statement of a material fact.

(e) That the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain the records or to make required reports, or the applicant has refused to permit access to, or copying or verification of, the records.

(f) That on the basis of new information before the department, evaluated together with the evidence before it when the application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the new drug or device are inadequate to assure and preserve its identity, strength, quality, purity, composition, and characteristics as determined by qualified experts

selected by the department, and were not made adequate within a reasonable time after receipt of written notice from the department specifying the matter complained of.

(g) That on the basis of new information before it, evaluated together with the evidence before it when the application was approved, the labeling or advertisement of the new drug or device, based on an evaluation of all material facts, is false or misleading in any particular and is not corrected within a reasonable time after receipt of written notice from the department specifying the matter complained of.

111580. When the department finds that there is an imminent hazard to the public health, it may suspend the approval for the application immediately.

111585. An order pursuant to Section 111575 or 111580 withdrawing approval of an application concerning any new drug or device shall be revoked whenever the department finds that the facts justify the action.

111590. Section 111550 does not apply to a drug or device intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs or devices if the investigation is conducted in accordance with the requirements of Section 505(i) of the federal act (21 U.S.C. Sec. 355(i)) or Section 520(g) thereof (21 U.S.C. Secs. 352 and 360) and the regulations adopted pursuant to the federal act.

111595. Section 111550 does not apply to any drug or device intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs or devices if all the following conditions are complied with:

(a) The submission to the department, before any clinical testing of a drug or device is undertaken, of reports, by the manufacturer or the sponsor of the investigation of the drug or device, of preclinical tests including tests on animals, of the drug or device adequate to justify the proposed clinical testing.

(b) The manufacturer or the sponsor of the investigation of a drug or a device proposed to be distributed to investigators for clinical testing obtaining a signed, notarized agreement from each of the investigators that patients to whom the drug or device is administered will be under his or her personal supervision, or under the supervision of investigators responsible to him or her, and that he or she will not supply the drug or device to any other investigator, or to clinics, for administration to human beings.

(c) The establishment and maintenance of the records, and the making of the reports to the department, by the manufacturer or the sponsor of the investigation of the drug or device, of data, including but not limited to, analytical reports by investigators, obtained as a result of the investigational use of the drug or device, as the department finds will enable it to evaluate the safety and effectiveness of the drug or device in the event of the filing of an application pursuant to Section 111550.

(d) The manufacturer, or the sponsor of the investigation, require experts using the drugs or devices for investigational purposes to certify to the manufacturer or

sponsor that they will comply with the requirements of Article 4 (commencing with Section 111515).

(e) Any other conditions as the department shall adopt as regulations necessary for the protection of the public health. The federal regulations adopted pursuant to Section 505(i) of the federal act (21 U.S.C. Sec. 355(i)) or Section 520(g) thereof (21 U.S.C. Secs. 352 and 360) shall be the regulations for exemptions from Section 111550 in this state. However, the department may prescribe, by regulation, any condition for exemption from Section 111550 whether or not the condition is in accordance with regulations adopted under the federal act.

111600. (a) In making determinations on requests for approval of AIDS-related drugs, as defined in subdivision (b), in accordance with Section 111550, or for exemptions from these requirements, for purposes of investigations of these drugs, pursuant to Section 111595, the department shall employ persons to conduct reviews of requests for drug marketing approval for AIDS-related drugs, or exemptions from the approval requirements as specified in that section. The AIDS Vaccine Research and Development Advisory Committee shall review and advise the department in its actions under this section.

Where necessary, the department shall enter into contracts with appropriate and qualified persons or entities for the review of these requests, including persons with significant experience in conducting or reviewing clinical trials of drugs or physicians with significant experience in treating AIDS patients.

No person may contract with the department for the review of a request under this subdivision if the person has a financial interest or a conflict of interest involving the drug being evaluated.

(b) "AIDS-related drug" means either of the following:

(1) A vaccine to protect against human immunodeficiency virus (HIV) infection.

(2) Antiviral agent, immune modulator, or other agent to be administered to persons who have been infected with HIV, to counteract the effects of this infection, or any drug to treat opportunistic infections associated with AIDS.

(c) The department, not later than July 1, 1988, and annually thereafter, shall report to the Legislature on the activities conducted pursuant to this section.

(d) The immunities provided for in Sections 818.4 and 821.6 of the Government Code shall apply whenever the department grants approval pursuant to Section 111550 or an exemption from the approval requirements pursuant to Section 111595, for an AIDS-related drug.

111605. (a) In making determinations on requests for approval of AIDS-related drugs, as defined in subdivision (b), in accordance with Section 111550, or for exemptions from these requirements, for purposes of investigations of these drugs, pursuant to Section 111595, the department shall employ persons to conduct reviews of requests for drug marketing approval for AIDS-related drugs, or exemptions from the approval requirements as specified in that section. The AIDS Vaccine Research and Development Advisory Committee shall review and advise the department in its actions under this section.

Where necessary, the department shall enter into contracts with appropriate and qualified persons or entities for the review of these requests, including persons with significant experience in conducting or reviewing clinical trials of drugs or physicians with significant experience in treating AIDS patients.

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(b) "AIDS-related drug" means either of the following:

(1) A vaccine to protect against human immunodeficiency virus (HIV) infection.

(2) Antiviral agent, immune modulator, or other agent to be administered to persons who have been infected with HIV, to counteract the effects of this infection, or any drug to treat opportunistic infections associated with AIDS.

(c) The immunities provided for in Sections 818.4 and 821.6 of the Government Code shall apply whenever the department grants approval pursuant to Section 111550 or an exemption from the approval requirements pursuant to Section 111595, for an AIDS-related drug.

111610. Section 111550 does not apply to any of the following:

(a) A drug or device that is sold in this state, or introduced into interstate commerce, at any time prior to the enactment of the federal act, if its labeling and advertising contained the same representations concerning the conditions of its use.

(b) Any drug that is licensed under the Public Health Service Act of July 1, 1944 (58 Stats. 682, as amended; 42 U.S.C. Sec. 201 et seq.) or under the eighth paragraph of the heading of Bureau of Animal Industry of the act of March 4, 1913 (37 Stat. 832-833; 21 U.S.C. Sec. 151 et seq.), commonly known as the "Virus-Serum-Toxin Act."

(c) Any antibiotic drug that is subject to Section 111445.

ARTICLE 6. Licenses

111615. No person shall manufacture any drug or device in this state unless he or she has a valid license from the department. The license is valid for one calendar year from the date of issue, unless it is revoked. The license is not transferable.

The department may require any manufacturer, wholesaler, or importer of any prescription ophthalmic device in this state to obtain a license.

111620. A separate license is required for each place of manufacture.

111625. A license application shall be completed annually and accompanied by an application fee as prescribed in Section 111630. This fee is not refundable if the license is refused.

111630. The department shall by regulation establish the application form and set the fee for licensure and renewal of a license. The penalty for failure to apply for renewal of a license within 30 days after its expiration is ten dollars ($10) and shall be added to the renewal fee and be paid by the applicant before the renewal license may be issued. All moneys collected as fees shall be expended when appropriated by the Legislature in

the carrying out of the provisions of this part and the regulations adopted pursuant to this part.

Any person licensed pursuant to this section shall immediately notify the department of any change in the information reported in the license application.

111635. Prior to issuing or renewing a license required by Section 111615, the department shall inspect each place of business to determine ownership, adequacy of facilities, and personnel qualifications.

111640. The department shall make investigations or inspections authorized by Article 2 (commencing with Section 110410) of Chapter 2 as it deems necessary to carry out this chapter.

111645. Any violation of any provision of this part or any regulation adopted pursuant to this part shall be grounds for denying a license or for suspending or revoking a license. Proceedings for the denial, suspension, or revocation of a license shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code, and the department shall have all the powers granted in that chapter.

111650. Drug manufacturers who have obtained a license or who are applying for a license pursuant to this article shall submit to the California State Board of Pharmacy information as the Board of Pharmacy deems reasonably necessary to carry out its drug distribution responsibilities including, but not limited to, information on drug inventories or restricted dangerous drugs. Failure of any manufacturer to report the information to the Board of Pharmacy in a timely fashion shall be grounds for the department to deny, suspend, or revoke the manufacturer's license.

The California State Board of Pharmacy may adopt regulations that are reasonably necessary to implement this section.

111655. The licensing provisions of this chapter shall not apply to any of the following:

(a) Any pharmacy that maintains establishments in conformance with provisions of the Pharmacy Law, Chapter 9 (commencing with Section 4000) of Division 2 of the Business and Professions Code, regulating the practice of pharmacy, and that is regularly engaged in dispensing prescription drugs or devices, upon prescriptions of any person licensed to administer the drugs or devices to patients under the care of the person in the course of his or her professional practice, and that does not manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of his or her business of dispensing or selling drugs or devices at retail.

(b) Any pharmacy that solely engages in providing drugs or devices to a person licensed by law to administer the drug or device for his or her use in the course of his or her professional practice.

(c) Any pharmacy that solely provides drugs or devices to another pharmacy in order to meet a temporary inventory shortage.

(d) Any person who is licensed by law to prescribe or administer drugs or devices and who manufactures, prepares, propagates, compounds, or processes drugs or devices solely for use in the course of his or her professional practice.

(e) Any person who manufactures, prepares, propagates, compounds, or processes any drug or device solely for use in nonclinical research, teaching, or chemical analysis and not for sale.

(f) Any wholesaler, as defined in Section 4038 of the Business and Professions Code.

(g) Any such other class of persons as the department may by regulation exempt from the application of this article upon a finding that licensing by a class of persons in accordance with this article is not necessary for the protection of the public health.

(h) Any registered dispensing optician licensed pursuant to the provisions of Chapter 5.5 (commencing with Section 2550) of Division 2 of the Business and Professions Code, who is regularly engaged in dispensing or selling prescription lenses and frames, and not engaged in the manufacture, preparation, processing or assembling of lenses or frames for sale other than in the regular course of his or her business of dispensing or selling lenses or frames at retail.

CHAPTER 7. COSMETICS

ARTICLE 1. General Provisions and Definitions

111660. As used in this chapter, "hair dye" does not include any eyelash dye or eyebrow dye.

111665. Any color additive shall be considered unsafe for use with respect to any cosmetic unless there is in effect a regulation adopted pursuant to Section 110090 that prescribes its use in cosmetics.

ARTICLE 2. Adulterated Cosmetics

111670. A cosmetic is adulterated if it bears or contains any poisonous or deleterious substance that may render it injurious to users under the conditions of use prescribed in the labeling or advertisement of the cosmetic, or under conditions of use as are customary or usual.

111675. Section 111670 shall not apply to coal tar hair dye, that is conspicuously labeled as follows:

"Caution--this product contains ingredients that may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness."

The labeling shall also bear adequate directions for such preliminary testing.

111680. Any cosmetic is adulterated if it consists in whole or in part of any filthy, putrid, or decomposed substance.

111685. Any cosmetic is adulterated if it has been produced, prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

111690. Any cosmetic is adulterated if its container is composed, in whole or in part, of any poisonous or deleterious substance that may render the contents injurious to health.

111695. Any cosmetic is adulterated if it is not a hair dye and it is, or it bears or contains, a color additive that is unsafe within the meaning of Section 111665.

111700. It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any cosmetic that is adulterated.

111705. It is unlawful for any person to adulterate any cosmetic.

111710. It is unlawful for any person to receive in commerce any cosmetic that is adulterated or to deliver or proffer for delivery any such cosmetic.

111715. While any regulation relating to any color additive referred to in Section 111665 is in effect, any cosmetic that bears or contains a color additive in accordance with these regulations shall not be considered adulterated.

111720. Any cosmetic intended for export shall not be deemed to be adulterated under this part if it satisfies all of the following requirements:

(a) It accords to the specifications of the foreign purchaser.

(b) It is not in conflict with the laws of the importing country.

(c) It is labeled on the outside of the shipping package to show that it is intended for export.

If the article is sold or offered for sale in domestic commerce, this section shall not exempt it from any of the provisions of this part.

111725. A cosmetic is deemed adulterated under the laws of this state if it is subject to regulations issued by the United States Food and Drug Administration relating to tamper-resistant packaging, as set forth in Part 700 of Volume 21 of the Code of Federal Regulations, as amended, but is not in compliance therewith.

ARTICLE 3. Misbranded Cosmetics

111730. Any cosmetic is misbranded if its labeling is false or misleading in any particular.

111735. Any cosmetic is misbranded if its labeling or packaging does not conform to the requirements of Chapter 4 (commencing with Section 110290).

111740. Any cosmetic is misbranded if it is in package form and it does not bear a label containing all of the following information:

(a) The name and place of business of the manufacturer, packer, or distributor.

(b) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count.

Reasonable variations shall be permitted from the requirements of subdivision (b) of this section. Requirements for placement and prominence of the information and exemptions as to small packages shall be established by regulations adopted pursuant to Section 110380.

111745. A cosmetic is misbranded if any word, statement, or other information required pursuant to this part to appear on the label or labeling is not prominently placed upon the label or labeling with conspicuousness, as compared with other words, statements, designs, or devices, in the labeling, and in terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

111750. Any cosmetic is misbranded if its container is so made, formed, or filled as to be misleading.

111755. A cosmetic is misbranded if it is a color additive, unless its packaging and labeling are in conformity with the packaging and labeling requirements applicable to color additives prescribed under the provisions of Section 110090. This section does not apply to packages of color additives that, with respect to their use for cosmetics, are marketed and intended for use only in or on hair dyes.

111760. Any cosmetic is misbranded if its packaging or labeling is in violation of an applicable regulation issued pursuant to Section 108685 or 108700.

111765. It is unlawful for any person to manufacture, or sell any cosmetic that is misbranded.

111770. It is unlawful for any person to misbrand any cosmetic.

111775. It is unlawful for any person to receive in commerce any cosmetic that is misbranded, or to deliver or proffer for delivery any cosmetic.

111780. It is unlawful for any person to alter, mutilate, destroy, obliterate, or remove the label or any part of the labeling of any cosmetic if the act results in the cosmetic being misbranded, while held for sale.

111785. Any cosmetic intended for export shall not be deemed to be misbranded under this part if it satisfies all of the following requirements:

(a) It accords to the specifications of the foreign purchaser.

(b) It is not in conflict with the laws of the country to which it is intended for export.

(c) It is labeled on the outside of the shipping package to show that it is intended for export.

If the article is sold or offered for sale in domestic commerce, this section shall not exempt it from any of the provisions of this part.

111790. A cosmetic is deemed misbranded under the laws of this state if it is subject to regulations issued by the United States Food and Drug Administration relating to tamper-resistant packaging, as set forth in Part 700 of Volume 21 of the Code of Federal Regulations, as amended, but is not in compliance therewith.

ARTICLE 4. Voluntary Registration

111795. (a) Any person who manufactures a cosmetic in this state may register with the department. Any registration issued under this article shall be valid for one calendar year from the date of issue, unless it is suspended or revoked. The registration shall not be transferable.

(b) A separate registration shall be required for each place of manufacture.

111800. A registration application form provided by the department shall be completed annually and accompanied by an application fee of three hundred fifty dollars ($350). This fee shall not be returnable if the registration is denied. The fee amount shall be adjusted annually pursuant to Section 100425. All fees collected pursuant to this section shall be deposited into the Export Document Program Fund established by Section 110240.

111805. Any person registered pursuant to this article shall immediately notify the department of any change in the information reported in the registration application.

111810. (a) Prior to issuing a registration under Section 111795, the department shall inspect each place of business to determine ownership, adequacy of facilities, personnel qualifications, and compliance with this part. The department shall annually inspect each registrant.

(b) The department shall provide to each registrant a validated copy of the completed registration application form, sent to the mailing address shown on the form, as evidence of valid registration.

111815. The department shall make any investigations or inspections authorized by Article 2 (commencing with Section 110410) of Chapter 2 as it deems necessary to carry out this article.

111820. Any violation of this part or any regulation adopted pursuant to this part shall be grounds for denying a registration or for suspending or revoking a registration. Proceedings for the denial, suspension, or revocation of the registration shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of

Division 3 of Title 2 of the Government Code, and the department shall have all the powers granted in that chapter.

CHAPTER 8. PENALTIES AND REMEDIES

ARTICLE 1. Penalties

111825. Any person who violates any provision of this part or any regulation adopted pursuant to this part shall, if convicted, be subject to imprisonment for not more than one year in the county jail or a fine of not more than one thousand dollars ($1,000), or both the imprisonment and fine. If the violation is committed after a previous conviction under this section that has become final, or if the violation is committed with intent to defraud or mislead, the person shall be subject to imprisonment for not more than one year in the county jail, imprisonment in state prison, or a fine of not more than ten thousand dollars ($10,000), or both the imprisonment and fine.

111830. Upon conviction of any violation of this part, or any regulation adopted pursuant to this part, the court may require, as a condition of probation under Section 1203.1 of the Penal Code, that the defendant pay to the department the reasonable costs incurred by the department in investigating and prosecuting the action, including, but not limited to, the costs of storage and testing. This payment shall be in addition to any other costs that a court is authorized to require a defendant to pay under Section 1203.1 of the Penal Code.

111835. One-half of all fines collected by any court or judge for any violation of any provision of this part shall be paid into the State Treasury to the credit of the General Fund.

ARTICLE 2. Proceedings

111840. The Attorney General, any district attorney, or any city attorney to whom the department reports any violation of this part shall begin appropriate proceedings in the proper court.

111845. The department is not required to institute proceedings under this part for minor violations of this part, if the department believes that the public interest will be adequately served in the circumstances by a suitable written notice or warning.

111850. When the state asserts a violation of this part, the state need not negative any exemption or exception from the requirements of this part in any pleading or in any trial, hearing, or other proceeding. The burden of proof with respect to any exemption or exception rests upon the person claiming its benefit.

111855. (a) If any person violates any provision of this part, or any regulation adopted pursuant to this part, the department may assess a civil penalty against that person as provided by this section.

(b) The penalty may be in an amount not to exceed one thousand dollars ($1,000) per day. Each day a violation continues shall be considered a separate violation.

(c) If, after examination of a possible violation and the facts surrounding that possible violation, the department concludes that a violation has occurred, the department may issue a complaint to the person charged with the violation. The complaint shall allege the acts or failures to act that constitute the basis for the violation and the amount of the penalty. The complaint shall be served by personal service or by certified mail and shall inform the person so served of the right to a hearing.

(d) Any person served with a complaint pursuant to subdivision (c) of this section may, within 20 days after service of the complaint, request a hearing by filing with the department a notice of defense. A notice of defense is deemed to have been filed within the 20-day period if it is postmarked within the 20-day period. If a hearing is requested by the person, it shall be conducted within 90 days after the receipt by the department of the notice of defense. If no notice of defense is filed within 20 days after service of the complaint, the department shall issue an order setting the penalty as proposed in the complaint unless the department and the person have entered into a settlement agreement, in which case the department shall issue an order setting the penalty in the amount specified in the settlement agreement. When the person has not filed a notice of defense or where the department and the person have entered into a settlement agreement, the order shall not be subject to review by any court or agency.

(e) Any hearing required under this section shall be conducted by a departmental hearing officer appointed by the director. The department shall adopt regulations establishing a hearing process to review complaints. Until the department adopts these regulations, all hearings shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code, except that hearings shall be conducted by a departmental hearing officer appointed by the director. The department shall have all the powers granted in that chapter.

(f) Orders setting civil penalties under this section shall become effective and final upon issuance thereof, and payment shall be made within 30 days of issuance. A copy of the order shall be served by personal service or by certified mail upon the person served with the complaint.

(g) Within 30 days after service of a copy of a decision issued by the director, any person so served may file with the superior court a petition for writ of mandate for review of the decision. Any person who fails to file the petition within this 30-day period may not challenge the reasonableness or validity of the decision or order of the director in any judicial proceeding brought to enforce the decision or order or for other remedies. Section 1094.5 of the Code of Civil Procedure shall govern any proceedings conducted pursuant to this subdivision. In all proceedings pursuant to this subdivision, the court shall uphold the decision of the director if the decision is based upon substantial evidence in the whole record. The filing of a petition for writ of mandate shall not stay any corrective action required pursuant to this part or the accrual of any penalties assessed pursuant to this section. This subdivision does not prohibit the court from granting any appropriate relief within its jurisdiction.

(h) The remedies under this section are in addition to, and do not supersede, or limit, any and all other remedies, civil or criminal.

ARTICLE 3. Seizure and Embargo

111860. Whenever an authorized agent of the department finds, or has probable cause to believe, that any food, drug, device, or cosmetic is adulterated, misbranded, or falsely advertised within the meaning of this part, or the sale of any food, drug, device, or cosmetic would be in violation of this part, that agent shall affix to the food, drug, device, cosmetic, or component thereof, a tag or other appropriate marking. He or she shall give notice that the food, drug, device, or cosmetic is, or is suspected of being, adulterated, misbranded, falsely advertised, or the sale of which would be in violation of this part and has been embargoed, and that no person shall remove or dispose of the food, drug, device, or cosmetic by sale or otherwise until permission for removal or disposal is given by an authorized agent of the department or the court.

111865. It is unlawful for any person to remove, sell, or dispose of a detained or embargoed food, drug, device, or cosmetic without permission of an authorized agent of the department or the court.

111870. When an authorized agent of the department has found that a food, drug, device, or cosmetic that is embargoed, is not adulterated, misbranded, falsely advertised, or the sale of which is not otherwise in violation of this part, that agent shall remove the tag or other marking.

111875. When an authorized agent of the department finds, or has reasonable cause to believe, that the embargo will be violated, that agent may remove the embargoed food, drug, device, or cosmetic to a place of safekeeping.

111880. When a food, drug, device, or cosmetic is alleged to be adulterated, misbranded, falsely advertised, or the sale of which is otherwise in violation of this part, the department shall commence proceedings in the superior court or lower court in whose jurisdiction the food, drug, device, or cosmetic is located, for condemnation of the article.

111885. If the court finds that an embargoed food, drug, device, or cosmetic is adulterated, misbranded, falsely advertised, or the sale of which is otherwise in violation of this part, the food, drug, device, or cosmetic shall, after entry of the judgment, be destroyed at the expense of the claimant or owner, under the supervision of an authorized agent of the department. All court costs and fees and all reasonable costs incurred by the department in investigating and prosecuting the action, including, but not limited to, the costs of storage and testing, shall be taxed against the claimant or owner of the food, drug, device, or cosmetic or his or her agent. When the adulteration or misbranding can be corrected by proper labeling or processing of the food, drug, device, or cosmetic, or when the false advertisement can be corrected and when all provisions of this part can be complied with, then, after entry of the judgment and after costs, fees, and expenses have been paid and a good and sufficient bond, conditioned that the food, drug, device, or cosmetic will be brought into compliance, the court may, by order,

direct that the food, drug, device, or cosmetic be delivered to the claimant or owner to be brought into compliance by labeling, processing, or other means under the supervision of an authorized agent of the department. The expense of the supervision shall be paid by the claimant or owner. The bond shall be discharged when the court finds that the food, drug, device, or cosmetic is no longer held for sale in violation of this part and that all of the expenses of supervision have been paid.

111890. Whenever an authorized agent of the department finds any meat, meat products, seafood, poultry, vegetable, fruit, or other food that is unsound, or that contains any filthy, decomposed, or putrid substance, or that may be poisonous or deleterious to health, or otherwise unsafe, that agent may declare the food to be a nuisance and the department, or its authorized agent, shall condemn or destroy it, or render it unsalable as human food by decharacterization.

111895. Any superior or lower court of this state may condemn any food, drug, device, or cosmetic under provisions of this part. In the absence of such an order, the food, drug, device, or cosmetic may be destroyed under the supervision of an authorized agent of the department who has the written consent of the owner, his or her attorney, or authorized representative.

ARTICLE 4. Injunctions

111900. The Attorney General or any district attorney, on behalf of the department, may bring an action in superior court and the court shall have jurisdiction upon hearing and for cause shown, to grant a temporary or permanent injunction restraining any person from violating any provision of this part. Any proceeding under the provisions of this section shall conform to the requirements of Chapter 3 (commencing with Section 525) of Title 7 of Part 2 of the Code of Civil Procedure, except that the department shall not be required to allege facts necessary to show, or tending to show, lack of adequate remedy at law, or to show, or tending to show, irreparable damage or loss.

111905. In addition to the injunctive relief provided in Section 111900, or as a nonpunitive alternative to Section 111915, the court, after finding any person has violated this part, shall award to the department all reasonable costs incurred by the department in investigating and prosecuting the action, including, but not limited to, the costs of storage and testing, as determined by the court. The award shall be paid to the department by the person found by the court to have violated this part.

111910. (a) Notwithstanding the provisions of Section 111900 or any other provision of law, any person may bring an action in superior court pursuant to this section and the court shall have jurisdiction upon hearing and for cause shown, to grant a temporary or permanent injunction restraining any person from violating any provision of Article 7 (commencing with Section 110810) of Chapter 5. Any proceeding under this section shall conform to the requirements of Chapter 3 (commencing with Section 525) of Title 7 of Part 2 of the Code of Civil Procedure, except that the person shall not be required to

allege facts necessary to show, or tending to show, lack of adequate remedy at law, or to show, or tending to show, irreparable damage or loss, or to show, or tending to show, unique or special individual injury or damages.

(b) In addition to the injunctive relief provided in subdivision (a), the court may award to that person, organization, or entity reasonable attorney's fees as determined by the court.

(c) This section shall not be construed to limit or alter the powers of the department and its authorized agents to bring an action to enforce this chapter pursuant to Section 111900 or any other provision of law.

111915. In addition to injunctive relief, the court may impose as a civil penalty, damages in the maximum sum of one thousand dollars ($1,000) for each day the violation is continued. Damages shall be paid one-half to this state and one-half to the county in which the action is brought if brought by the Attorney General, or entirely to the county if brought by a district attorney.